HIT Policy Committee
Final Transcript
March 2, 2011

Presentation

Judy Sparrow – Office of the National Coordinator – Executive Director
Good morning, everybody and welcome to the 21st meeting of the HIT Policy Committee. Just a reminder, this is a Federal Advisory Committee. There will be opportunity at the end of the meeting for the public to make comments and there will be a transcript made available on the ONC Website. Also, a reminder for committee members to please identify yourselves when speaking.

Let's go around the room and introduce ourselves, starting on my left with Marc Probst.

Marc Probst – Intermountain Healthcare – CIO
Marc Probst, Intermountain Healthcare.

Gayle Harrell – Florida – House of Representatives
Gayle Harrell, Florida House of Representatives.

Judy Faulkner – Epic Systems – Founder
Judy Faulkner, Epic.

David Lansky – Pacific Business Group on Health – President & CEO
David Lansky, Pacific Business Group on Health.

Deven McGraw – Center for Democracy & Technology – Director
Deven McGraw, Center for Democracy & Technology.

David Blumenthal – Department of HHS – National Coordinator for Health IT
David Blumenthal, Office of the National Coordinator.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Paul Tang, Palo Alto Medical Foundation.

Paul Egerman – Software Entrepreneur
Paul Egerman, Software Entrepreneur.

Neil Calman – Institute for Family Health – President & Cofounder
Neil Calman, Institute for Family Health.

Christine Bechtel – National Partnership for Women & Families – VP
Christine Bechtel, National Partnership for Women & Families.

Madhu Agarwal – Department of Veterans Affairs
Madhu Agarwal, Department of Veterans Affairs.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
Larry Wolf for Rick Chapman, Kindred Healthcare.

Adam Clark – FasterCures – Director, Scientific & Federal Affairs
Adam Clark, FasterCures.

Judy Sparrow – Office of the National Coordinator – Executive Director
I believe we have a number of members on the telephone. Scott White, are you there? Charles Kennedy? Connie Delaney?

Connie Delaney – University of Minnesota School of Nursing – Dean
Yes.

Judy Sparrow – Office of the National Coordinator – Executive Director
I'll turn it over to Dr. Blumenthal.

Jim Borland – SSA – Special Advisor for Health IT, Office of the Commissioner
Judy, this is Jim Borland. I'm on the line as well.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Thank you all for being here. I won't make much in the way of remarks today. In between these last two meetings some of us traveled to Orlando to be at the HIMSS meeting, and I think, judging by the size of that meeting, the Federal Government seems to be having an impact, at least the industry's growing and the people involved in this field. I don't know if that's the ultimate judge of our metric for success of the HITECH agenda, but it's certainly interesting.

Anyway, we have mostly a set of reports today from groups that are working hard. We do have one set of recommendations to consider from our Health Information Exchange Workgroup on authentication, and given how late those recommendations came out, and we do of course appreciate the hard work of the Exchange Workgroup and know that sometimes it's hard to get recommendations done precisely when they need to be. But it may be necessary for us to hear that report and then to give members of the committee a chance to digest and then consider them either at a later meeting or at a phone meeting in between this meeting and the next one, which I believe is scheduled for April 15th. ...?

Judy Sparrow – Office of the National Coordinator – Executive Director
Yes.

W
The 13th.

M
The 13th.

Judy Sparrow – Office of the National Coordinator – Executive Director
All right. Sorry, I'll double check that. We can do both. No, I'll double check and make sure.

David Blumenthal – Department of HHS – National Coordinator for Health IT
We don't need an act of Congress to clarify this, I don't think. So we will make sure that everyone knows what the actual date is. Anyway, if it is that soon we may in fact just delay the recommendation consideration until that time, but we will let you know. I'm going to now turn the review of the agenda over to Paul Tang, who is to my left and as usual is both prepared and able to take it to the next step.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Thank you, David. Before we do that, why don't we take a look at the minutes and see if we have a motion to approve the minutes.

M
....

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Okay, thank you. Any further additions, discussions? All in favor?

W
Aye.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
All opposed? Any abstentions? Thank you.

As David said, we have a number of reports. It begins with the Quality Measures Workgroup, which has been working very hard on how to update the nation's quality measures considering the availability of electronic health record systems and interoperability Health Information Exchange. So we'll have an update from that group prior to them sending out some RFPs to measure developers. Then the Privacy and Security Tiger Team will discuss authentication of users and present some of the considerations in terms of, especially for users off campus, in a sense. Paul Egerman and Bill Stead will update us on the PCAST hearing they had, which many of the committee members attended here, as well as the Standards Committee. Then after lunch, we'll hear from the Information Exchange Workgroup with information that went out this morning, as Dr. Blumenthal mentioned, so we can postpone a vote until a later time and maybe not until the April meeting. Then we'll finish with public comments.

If there are no other changes, I'll turn it back to Dr. Blumenthal for our first update.

David Blumenthal – Department of HHS – National Coordinator for Health IT
I will turn around and turn it over to David Lansky or Tom Tsang or both.

David Lansky – Pacific Business Group on Health – President & CEO
Both, I hope. Tom, do you want to ...?

Tom Tsang – ONC – Medical Director
....

David Lansky – Pacific Business Group on Health – President & CEO
Good morning, everyone. Thank you, Dr. Blumenthal. We're reporting on the progress made in the Quality Measures Workgroup and we actually had a very thorough discussion, which is reflected in the minutes we just looked at for the last meeting. So I don't think in today's time we necessarily need to go down each of the tracks and each of the domains that were surfaced in the last meeting, although we certainly can come back to those. This is probably as much as anything a process check about where we are in the overall attempts to enhance the quality measures available for evaluating meaningful use.

With that, we do have some materials that you had a chance, I hope, to look over that came out in the packet. What I thought we'd do today is quickly first let me thank the staff again. They've been just phenomenal the last couple of months and are going through a huge amount of material supplied by public commenters and researchers and methodologists to try to help us understand what was realistic in advancing a quality measurement agenda that could be enhanced by Health IT. I think we're in a good place to give you a snapshot of where we are in the process thanks to their work.

The next slide summarizes where we were with the stage one clinical quality measurement approach. As you recall, in stage one the current implementation of the program eligible professionals had to report on three required core clinical quality measures, and if they didn't have qualifying patients in those core areas they could select from a set of alternate quality measures. In addition, they could select three measures, typically by sub-specialty area, and you probably all recall in the rule the tables of measures that were available to be used by physicians qualifying for the program. The next slide just summarizes, that was the structure that we had used for the clinical quality measurement reporting in stage one.

Then the next slide lists the core measures, the alternate measures, and just summarizes the structure of the menu set, as we called it, to allow people in the various specialties to pick measures of particular relevance to them. It is not a given that this same structure is the right structure to pursue for stage two and stage three, but we're obviously starting there. What I think we're undertaking now is to develop a

larger library of measures that address the domains we've all talked about in these meetings that could permit us to develop a different kind of structure to capture quality reporting in this program.

Now, we don't know what that is yet, so one of the tasks coming forward for the Quality Measures Workgroup will be to evaluate whether there is an opportunity to change this reporting structure in light of a new set of measures being available that weren't available last time around. The new pool of measures that is in play, in development, is illustrated by this next slide, which suggests that for stage two and stage three we have at least two new bundles of measures to consider for evaluating quality performance. The one on the left of this tree diagram that says "ONC De Novo Measures" would be some set of measures coming through the process that's underway this year, in 2011. In a development pipeline to take a set of good ideas and measure concepts that have surfaced from the public comment and put them out for additional refinement and technical development by the experts. Hopefully by the end of this year the experts deem them fit, and reconsider them for use in stage two and stage three clinical quality assessment. Those have to be assessed in terms of methodology evidence standards, feasibility and so on.

The second pool of measures we can draw from in stage two and stage three are what we're calling "retooled measures," which come out of a pool of 113 measures that had previously been endorsed by NQF but for a more non-HIT based methodology, non-EHR based methodology. So now, they've been retooled so we can capture them from routine electronic data collection. We have the 69 retooled measures, which are the unduplicated 69 available measures, plus whatever comes out of this new pipeline will then go through a harmonization process with everything else the federal programs are considering for quality measurement. So that we don't end up chasing other strategies that PQRS or value-based payment systems or other programs might be looking at to try to harmonize all those. I think Tom's participating in some committees to do that, and then in addition come back to our process here at the Policy Committee to consider which of these measures seem to be consistent with our objectives in supporting of the meaningful use program.

That's the road map ahead. We have the retooled measures pretty much in hand. We are working this year on the de novo measures, and then all of that will come back through our process for consideration as part of stage two and potentially stage three.

Just to refresh your memory from the last two meetings, these are the domains that the workgroup has identified as being opportunities for new measurement that could fit into the meaningful use program, and within each of these domains, there has been additional levels of detail fleshed out. You have in your packet a one page or one and a half page summary grid which is probably the easiest thing to reference, it has a little bit of pink top border in your hard copy.

That grid, let me just summarize the structure of it for your review and then we can take a minute and discuss the content of it. The grid has, on the left hand rows, those five major headings that are the structure of our work, clinical appropriateness, population health, and so on. Then within each of those five major categories or domains, we have three or four sub-domains, depending on each category, and then within each of the sub-domains we have a proposed set of measures or measure concepts. Let me wait and see if people have caught up to the material. Deven is holding it. It's about halfway back in the packet. It's behind the long memorandum describing each of the measures in some detail.

Deven McGraw – Center for Democracy & Technology – Director
Yes, with ... paper separating the narrative from ....

David Lansky – Pacific Business Group on Health – President & CEO
Obviously today, I don't think we need to go through all the detail in here, but I just wanted you to have a feeling for the structure, and certainly you can respond to any questions. So for each domain list and sub-domains, these sub-domains then have proposed measures or measure concepts with a fair amount of detail, and in the long document you saw a little additional detail in each of these proposed measures. These then will be reviewed by the ONC staff, and potentially by other consultants, to develop them into something which hopefully can work within the meaningful use program at either stage two or stage three.

If you eyeball this entire portfolio, you'll have a sense of what is potentially available for assessing the meaningful use program in the next two cycles of implementation.

We talked at the last meeting about some of these in a little more detail, and as you can see, there are some methodological considerations cut across many of these. For example, acquiring data from multiple sources that is not only the EHR but perhaps claims data or another EHR or a hospital system, and integrating data from multiple settings of care, multiple points in time. We have some proposed measures that are longitudinal, where there's an initial measurement of blood glucose or lipid control and a subsequent measurement. We have to take them, which could be from different data systems, and then evaluate them and compare them to each other to see if there's been an improvement or not in a particular indicator. So there's some methodology challenges that are very important but valuable from the point of view of care coordination, integration and so on, and patient management.

That's the structure of where we are. Let me go back then to the slide deck. The timeline that we have in mind, given this overall approach, is with your support today and your comfort with our proceeding down this path I think ONC will then continue to develop these proposed measures and see which ones are in fact viable for the program. That would be something we hope you can do today and give us encouragement to go forward. Then ONC would then initiate measure development activities throughout the balance of this year, and as you see in the third bullet point, through the last half of this year the concepts and measures suitable for stage two would be defined given specifications and put out for public comment. Then in the subsequent 2012 period we would look at the completion of the stage two measures and of course then begin to consider the stage three measures, by which time hopefully we'd have more information about those as well from the consultants.

Let me just review some of the larger issues then that remain on the table. In effect, the Quality Measures Workgroup is reporting to you today on a body of work that we feel like we've taken to a certain transitional point, where now this matrix we just looked at goes back to the staff, and potentially contractors, for further development. The committee then will come back to the issues on this slide and begin to think about the structure of the quality measurement reporting program itself, leaving this more detailed specification work off to a technical process.

One broad issue for us to consider in the next few months as a committee is the framework for the stage two clinical quality measures. Do we continue with the model that we used in stage one of core measures balanced with specialty measures? Do we carry forward all the stage one measures? Do we carry forward the retooled NQF eHealth measures? That's a discussion we'd like to have a couple of minutes of reaction to today, your thoughts about stage one structure and whether to continue it or to consider changes to it.

A second broad measure, broad topic we want to take up is this question of capturing measures across settings of care and different data systems, a code that is going outside of the self-contained EHR for the purposes of clinical quality measurement. So here, it describes exchange and interoperability infrastructure that would let us capture data from multiple points to create a clinical quality measure.

The third methodological question we have in front of us is how to capture data for patients to report their own outcomes and their own experience of care, and here we've called it the available infrastructure. One theory is you could ask each individual physician or hospital with its own EHR platform to have an ability to capture data from its patients. Maybe that's not the most efficient or methodologically robust way to do it. Maybe there should be a third party platform, much as we do with patient surveys like CAPS, where an independent vendor or platform is used to communicate with patients and get their assessments. There are pluses and minuses to that question.

One opportunity we have is for data to come right back to the clinician for their use, because it is integrated into their data platform. The flip side of that is not having an independent arm's length relationship between the patient and their healthcare provider, so they can not feel somehow compromised in their ability to give an honest judgment about the care they're getting. So that's a tradeoff we'd like to have some dialogue about and do some work on. Then, making sure that the

standards and vocabulary development process is relevant to these measures. We do have some uniformity and agreement about the types of specifications we use for these measures, so those are all on the table for the committee to take up in parallel with the technical work on the specs.

So here are our next steps. These recommendations we're bringing to you today will hopefully inform ONC in its process on the measures for stage two and stage three. There may be a procurement process. That's something ONC, with its other agencies, will consider to do this measure development work. The Standards Committee, which is reenergizing its Quality Workgroup, will be taking up some of these questions I just posed in terms of the standards and vocabularies needed to support the eMeasures. There are other groups, including the Information Exchange Workgroup, that we'll hear from later today, which could be helpful in solving this infrastructure question and deciding what information exchange standards are needed to support quality measurement as a nice synergy between the different groups we have underway.

I think that's where we're at. So with that, let me see if Tom has additions that I may have omitted.

Tom Tsang – ONC – Medical Director
You summarized it very nicely. Thank you.

David Lansky – Pacific Business Group on Health – President & CEO
With that, maybe we should go back through this report and just check in and see if people have comments about some of the key elements that I've tried to capture for you here. Let me just go back to the review of stage one and how stages two and three, the opportunity to capture some new measures. Does anybody have any questions or reactions about the approach that we're taking to this?

David Blumenthal – Department of HHS – National Coordinator for Health IT
First, I want to thank you, and the members of the workgroup and my ONC colleagues, for the huge amount of work. Those of you who will remember previous presentations, we got hundreds of suggestions for new measures. They all had to be culled and correlated and subsumed under one another and put into a framework and then boiled down to some reasonable number and then related to high priorities and then put into a process that could be set up for the development of the measures and the commissioning of the work that's needed. So it was a very heavy lift and you've all done a terrific job of it.

I wanted to add that this process will give the federal government the chance to consider a broader range of measures than we had in stage one. And the opportunity to be more representative of the actual practice of health and medicine, include more specialties in the measures, though almost certainly we won't get to every specialty. That's just a feature of the current state of development of the metrics, and also to try to capture the power of electronic technologies to advance the state of the art in quality measurements. So those are all to the good. But these go into the funnel and then as the funnel narrows down what comes out the other end will be reflective of the input of this group and many others and the comments we got and the technical progress we made on tooling the measures and everything else.

One thing I want to say is that I'm hopeful that the federal government will, at least the Department of Health and Human Services using its ACA authorities, will have more focus in its own quality agenda, which may make it easier for us to decide which quality metrics make sense. We will also be watching what our colleagues at CMS do in their rule making around accountable care organizations, around value-based purchasing, around medical homes, and what the Center for Medicare and Medicaid innovation does, so that the federal government sends as consistent a message as we can about what its priority measures are. So that we are setting the stage electronically for a new system of data collection that has some future, that will extend into the future and will hopefully make it easier for providers to collect measures electronically that meet multiple program purposes, and thereby lessen the weight on providers.

It's also our hope, working with private stakeholders, that there will be some alignment between the federal government and private stakeholders about the measures that they are going to associate value

with in their own pay for performance and quality improvement initiatives. The Holy Grail here is a consistent set of electronic measures that are collectible electronically and can be rooted to the right target as payers and policy makers decide on their priorities. But this is an absolutely foundational piece of work to enable that future to happen, so our appreciation for the work you've done.

After that bit of oration, I'll let the rest of the group ask questions.

M
Gayle?

Gayle Harrell – Florida – House of Representatives
Thank you very much. I actually want to thank the group for the incredible work that you've done. I've read this in depth and I have several comments and questions. First of all, on the de novo measures, can you give us a little more idea on what the process is going to be to develop them so that we really have an in-depth understanding and making sure that these are going to be measures that are going to be validated through the traditional process? How are we going to do this? Are there outside groups that do measures going to be assisting the ONC in developing them yet tweaking them to make sure that they are measurable through electronic health records? Give us a little better sense of what that process is going to be and what the time frame is going to be. I don't know that you can go through a measure creation endeavor in the time frame to make them available for stage two.

David Lansky – Pacific Business Group on Health – President & CEO
Gayle, I think those are very good points, especially the last one. But this process really started last year, about six months ago, when we had tiger team members composed of all the measure stewards, NQF, NCQA, PCPI, a lot of the public stakeholders, a lot of the academic medical centers who actually do this type of work. So it really started six months ago when they started giving input on what's feasible, what's possible, what we should be doing as a country, what we should be thinking of in terms of new types of measures that would take advantage of all the capabilities of EHR. So with that said, I think now we're really funneling in and taking also the RFP comments, about 1,200 comments that we've received, and we really narrowed down to maybe the most promising measures that would be the most credible and that would be based on the evidence.

The next few months moving forward we're probably going to have a master contractor that's going to work with subject matter experts, technical experts, to look at the evidence, follow a blueprint that CMS has in terms of measure development, work with agencies and entities like NQF and look at the feasibility of endorsement, looking at a consensus body picture. In terms of the time frame, going back to what David was saying before that we're going to have to look at what measures are feasible within an eight month to one year time frame versus a two and a half year time frame. That's going to be ready for stage two we'll select, and those that won't be ready for stage two we'll think about in stage three.

W
... off on this, please. Certainly, the time frame is very short and you have to allow the Standards Committee adequate time. If you have the measure conceptualized then you need the Standards Committee to be sure that we do it. I just am concerned that going into a new endeavor such as this that we allow adequate time for vetting and for standards development so that the vendors can be out there and make sure that we have the integrated systems that enable the measurement, so just a word of caution there. After everyone's asked questions, I do want to go back to the exchange of the data and the care coordination elements. I have some questions on that as well, but I don't want to monopolize time.

M
Thanks, and I agree. This is just really well done, so thank you so much. This may be kind of a naïve question. David, you talked about the funnel and how it all comes together, two aspects. One, I think with the new technologies, the things that we have out there, we're getting new capabilities and new access to data, which may make some of the past quality measures irrelevant, or not as relevant as maybe another measure. I guess my example would be in diabetes we could go out and collect and have

a quality measure about the percentage of patients getting a checkup every six months that have to deal with that, or we could start looking at outcomes and what's the actual outcome of that population. I think now we can do that. We can do more of those outcomes based things. Where does that harmonization and optimization happen, because it seems to me there's a lot of challenges right now. CMS may be measuring on one thing and they've got tools actually in place that need specific measures, but those measures may not be as good as they used to be, or as what we now can go to. Who owns the authority to actually do that, balancing that harmonization? I know, it's an easy question.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Yes. The fact is that we have many coordinated mechanisms within the department. There's an inter-agency group on quality. There's an electronic quality measure group that represents CMS, AHRQ, ONC, and other organizations. Then there will be a rule making process that will, once the secretary signs off on a rule, will enable the public to comment the way it has at every point in our processes. As you've seen in the past, that comment period has significantly changed what we've included. If in a comment period we were to hear that there was a strong view that certain of our proposed measures were outdated and we shouldn't trouble providers with collecting them, then the likelihood is we would drop them, because we have no desire to perpetuate the collection of outmoded and not useful information.

What we're trying to do, as we always do, is to balance legislative mandates, some of which do require, for example, that CMS collect certain metrics because the Congress acted on the state of the art that existed when it passed HITECH and it passed ACA against the future opportunities that we face. And we are going to have to transition into electronically empowered measures because not everyone is going to be electronically capable. So if there are electronic ways of collecting older measures we may still meet to allow that to happen. It may still be easier to collect them electronically, although some of the ... collect them on paper just because that's the way the world will be.

Tony, do you want to comment on that?

Tony Trenkle – CMS – Director of OESS
I think you've summed it up pretty well, David. I think it's an evolution as opposed to getting everything perfectly synched up at once. Obviously, we know that there are multiple programs within CMS and other agencies that we'd have to begin to bring closer together. As David said, there are a number of groups looking at that. The problem, of course, is there's different timing of some of these which is going to make it difficult sometimes to perfectly harmonize things, at least in the short run. But we are actively working to make sure that over time, as soon as possible, that we can harmonize what's being done in meaningful use with what we're doing with accountable care organizations and other areas where we're going to be collecting quality measures. But it's not something that can be done every night because as David said, there's different statute mandates and different timing mechanisms which makes it somewhat difficult.

M
I think next is Larry.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
I'll add to the thanks for the great work that you guys have done and also to David's comments, because they were great, about the effort to get things aligned.

I'd like to actually maybe toss out a question more than an opinion here. We heard with the PCAST Report a notion of really focusing on atomic data, and the value of that in many ways is being able to feed the quality measures. Do you have any thoughts, having been immersed in these measures and watching the move from paper-based measures to eMeasures, or actually getting an understanding of what atomic data might be and the kinds of things you think would be important for us to take forward as we look more broadly at what the system should be doing?

David Lansky – Pacific Business Group on Health – President & CEO

My first reaction ... no, I don't think we've gotten to that level of analysis we're working at this really pragmatic short term question. One of the issues it raises for me, though, is where does the computation take place. We had the registry hearing now almost a year, a year and a half ago, and the question of who is the aggregator of data across individual contributors to a measure, especially as we get the care coordination of longitudinal measurements, is something we haven't sorted out. I think the more granular we expect the data sources to be, the more it raises the question of where is the locus of computation and analysis going to be. We have to somehow layer that question into this consideration of the PCAST model, for lack of a better word.

Tom Tsang – ONC – Medical Director
I think we started thinking about that in terms of thinking about a standardized approach in developing these measures. I think before, I guess in the pre-EHR era these measures, as we said, were based specifically on just claims and administrative data and chart review, and as we think about developing this universe of eMeasures we're going to need a standard dictionary. I think ONC is trying to develop that standard dictionary, or that standard data model and we're working intensely with the NQF on evolving their model called the QDM, the quality data model, which are standardized data elements that's cross-walked to standardized vocabulary sets. If we can get to a very, very universal, granular set of vocabulary sets that could be basically the foundation of all quality measures, most of those computational work will be done at the provider level and how that's going to be reported in aggregated will then be simply a policy issue.

David Lansky – Pacific Business Group on Health – President & CEO
I guess the subtext behind my question was we could endlessly iterate quality measures and really the goal is to start enabling the system to actually be rich data collectors so that people don't have to do a lot of re-work constantly to fill in the gaps.

Tom Tsang – ONC – Medical Director
Right and I think the QDM would resolve a lot of those issues.

David Lansky – Pacific Business Group on Health – President & CEO
That's great. So I'd encourage you to keep that in the discussion as you work through the measures of striving for the kind of consistency you're talking about with vocabularies and the data values themselves so that we don't get into oh, blood pressure is number/number. Well, it would actually be nice if there were numbers that we can calculate things off of them rather than having to parse the text all the time.

M
Paul?

Paul Egerman – Software Entrepreneur
I had a couple of comments. First, I want to respond to your comment, David, where you talked about who's going to do the calculation in the PCAST model. I think you have that same issue with what you're proposing right here. If you look at one of the first things on the first page, where you talk about asthma medication ratio and you say percentage of members, which the word "members" is interesting by itself in the document, but the issue is if you don't have a structure where there's a concept of members, who calculates this. I don't know the answer to that because the patient could be seen by several physicians for a particular problem.

I also have a comment that I have a concern that Gayle raised as it relates to stage two. It seems like we've got this harmonization process and there's a fair amount of detail and it's like the clock is ticking. I'm just a little nervous that we're going to be able to get as much done in stage two as you would like to get done. Assuming we do get a fair amount done in stage two, what happens with these measurements? As it relates to completing meaningful use, do these measurements get electronically submitted to CMS? Is this something that you would test that you completed it? What's going to happen once you actually complete this work, when the provider completes the work?

David Lansky – Pacific Business Group on Health – President & CEO

I think that's a policy problem we can speak to as a group here. I think the Quality Measures Workgroup can give some thought to it and come back with something for us to discuss here. Tony can speak more to the implementation options that CMS is envisioning at these next couple of milestones. Obviously, attestation is easier to implement and ultimately I think there's a hope that these can be reported as values and ultimately some of us would advocate they be reported as part of something like the quality reporting system for physicians. But there are several stages to get to public reporting of these results and they're not inherent in the meaningful use program. That's part of the harmonization question, how do these data get used by a variety of programs that these physicians and hospitals might be participating in. Tony, are you going to add something?

Tony Trenkle – CMS – Director of OESS
I don't know if I have too much to add there, David. But obviously this is an issue that we're looking at in terms of the timing and in terms of whether we have the infrastructure to support that. It gets into the whole harmonization issue, and this is one of the major factors we need to be looking at, or we are looking at, I should say.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Neil?

Neil Calman – Institute for Family Health – President & Cofounder
This has been a really interesting process to be a part of one of the subcommittees of the subcommittee of the committee. I say that because it's really easy to get down into the weeds here and for a provider like myself, I had an interesting experience a couple of weeks ago where somebody came in and we were bragging about our quality reporting system in our organization, which reports monthly on 42 quality measures. We developed it with the city health department a bunch of years ago. I love these graphs and these charts and things that come out of the system and they get automatically e-mailed to everybody. They sat there and they weren't as impressed with our work as I was, and at the end they said, so, who looks at these measures? I said, well, we send them out to all the medical directors and they meet with their staff about them. They said, what do you do with the data? I said, well, we've done work with five diabetes measures, we've done work with three depression measures, we've done work in a couple of areas, and that left thirty other measures that we've been reporting on for the last seven years that we've never really done anything about.

So I think there's a huge issue here in terms of our goal really as a nation is to improve quality, it's not just to look at quality, and there's a bunch of assumptions built into what we're doing that trouble me. One is that public reporting is going to automatically improve quality. Well, hell, we know that doesn't work the way we would love it to work. It might have some impact on it. Some other is that you just give the information to people and they're going to be somehow embarrassed. In fact, in our own organization, we give the information to people and most of them don't even ever look at it. We've had to put reminders in the system now to say please look at your diabetes reporting measures. I think we have to be, to me this has a couple of morals to it. One is, parsimony, with every letter capitalized, because you know doing 20 or 30 different measures that are going to be put out there for everybody. Even though I think there's probably 100 that are important, the truth of the matter is that an organization, even an organization as big as ours, can only focus on improvement in a couple of areas in any given year or two or three year sort of model. You can only focus on a couple of things. You can't really focus on improvement across some broad range of issues.

Second of all, there's an enormous amount of work that's going to go into this, and it almost feels like it's an end in and of itself. We sort of are just going on faith that at some point CMS or private payers or somebody's going to put something on the table that will make quality measurement into quality improvement. I think we have too much faith in that magic and we need to start thinking as a policy issue, in my mind, about how we make sure that that connection gets made.

So I think it goes back partially to what Paul said, partially to what you said, David, and that is, trying to think through now how do we connect these measures with something that from our point of view really drives us to be measuring meaningful use. Meaningful use to me is not producing a measure.

meaningful use to me is saying we need to see people doing something with some measures, and the complication with that is that in any given setting you want that to be relevant, the things that are most relevant and most important in that setting. So to the extent that we keep that a broad set of lots of measures, we actually might even be moving in a direction that says everybody's measuring the same thing, instead of really stimulating local use of data to do improvement in areas that a provider would find to be most important in their venue. That speech might have been as long as David's.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Paul, do you want to respond directly to that?

Paul Egerman – Software Entrepreneur
I want to respond to that and offer some hope and optimism about it, and partly out of experience from our group. I think measures are potent by their credibility. I think one of the things that we've been limited by is the available information, since Tom mentioned it's mostly been claims, it's mostly been administrative, and it actually is not that potent with the clinicians who are doing the job that you want them to do and subsequently the patients. Part of that is because we've got this indirect, and it turns out to be inaccurate and everybody sort of knows that and sort of reacts that way, a little bit with what Neil was saying, but we have the opportunity. I think this speaks to what Dr. Blumenthal mentioned, this conversion over to electronic clinical information that is basically a byproduct of practice gives us all a chance to form these new credible measures, the measures that physicians already believe in and they want to improve their score. That's a very, very powerful motivator. I think some of your de novo measures fit that bill.

The second piece is parsimony, and that's just a human attention thing, and that clearly is important and we need to work in our Policy Committee to make sure that we are parsimonious yet have things for the different specialties. The third is transparency. In our organization, for example, the transparency is that I can look up any physician in our practice and any of their individual scores. There's no secret number or anything like that. That's also powerful, especially when you have the credibility. So I want to speak to the motivation and the new era that Dr. Blumenthal is saying where we have the opportunity to produce better measures that are more credible and more empowering. I think that is going to be the magic sauce, Neil, that's going to change things and have your physicians look at it more if you combine credibility, parsimony and transparency.

Neil Calman – Institute for Family Health – President & Cofounder
How do we measure—?

Paul Egerman – Software Entrepreneur
Right now in our case transparency of physicians, I believe within just a matter of a few years it will be transparency of the patient. But the magic is because these are things that we actually talk to patients about we want to achieve a certain kind of goal because it's consistent with the guidelines, a lot of measures, sort of indirect measures.

Neil Calman – Institute for Family Health – President & Cofounder
A follow up comment, so the question is really how do we determine whether people are meaningfully using the data that's being put out there? That was really the issue in my mind. It's to say, a provider's going to have this stuff. Their EHR is going to automatically produce it, it's going to be credible, how do we determine? Our job is to determine that the systems are being meaningfully used.

David Lansky – Pacific Business Group on Health – President & CEO
I think we can come back to this. First, I want to give everyone the chance to ask their questions. Madhu?

Madhu Agarwal – Department of Veterans Affairs
I was actually going to make another statement. But just picking up on this thread on how does it become meaningful for a clinician, let me say—and I'll cite an example from ten years ago when we first started it—was our only electronic health record. Then with what we had perceived at that time to be our

evidence-based measures for diabetes, for hypertension, for congestive heart failure is started to use the information that we were getting from the electronic health record for each individual clinician in taking a look at their practices. There was a significant impact.

I will just cite one example of blood pressure. At the very start, the blood pressure measurements when they were done and for all those who had had blood pressure taken were diagnosed to have been hypertensive, and if their blood pressure was less than 140/90, the percentage at that time was 28%. So when you share that sort of information with the clinicians, they are bound to look at it because most of us believe that we are managing our patients exceedingly well. Over a period of time there are trends. But this time 73% of the patients that we see have very adequately managed blood pressure. This has happened with the use of certain electronic measures over that duration, whether it's through H2A1Cs or whatever else that we might be choosing. I believe that there are very strong case studies that have taught us over the number of years that there's a very important face for this in improving the overall outcomes.

I'll get back to what I was going to ask, or actually suggest. Again, great work. I had not been part of the various sub-groups so just looking at it, the health equity measure, great start. I think especially when it is brought up in the longitudinal set and not as episodic. I think there's also an opportunity to take into account not simply the gender and the race but also certain other factors such as urban or rural settings, education, and what have you, and the electronic health records can provide that platform to provide some stratification based on that.

My other two thoughts were around the adverse drug event. I think there's an opportunity here to expand to include images. The electronic health record is well suited to detect the creatinine or creatinine clearance both pre and post contrast, so I think that that would be an important one to consider. The second one I would suggest is also including hospital-acquired infections. So a patient who gets admitted with an acute MI has really no need to be on antibiotics, but with MRSA infections I think that can be easily detected by the EMR.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Thank you, Madhu. Judy?

Judy Faulkner – Epic Systems – Founder
A few things. First, I want to support Gayle in the comment of enough time. I think that's been talked about here. But it's not just for the vendors to develop the software, it's also for the healthcare organizations to install the software, to adapt the workflows and to train their users of the software. So the time frames have to be in there as well. Secondly, there was an interesting comment made by a physician at a board meeting last week, one of the healthcare organizations, and that was what percent of the U.S. population has a healthy BMI, not overweight, not obese, doesn't smoke, wears seat belts, and knows the importance of eating fruits and vegetables? The interesting thing was that most of us guessed way too high. The answer was 2.5% to 3%. So I think that really supports the need for these quality measures when you realize what that—

M
What about exercises regularly? If you throw that into the—

Judy Faulkner – Epic Systems – Founder
I was really glad they didn't put that one in.

M
Especially with ....

Judy Faulkner – Epic Systems – Founder
The last is a question for David and Tom. That is, maybe you explained this and maybe I just missed it, but when it says the core measures, they do three if the denominator's one. But if it's zero they can pick one of the others. My question is, what happens when you are a group practice, multi-specialty, and you

deal with adults and kids and your core measure is adult weight screening, then do you not do the kids because you don't have a zero for the adults? Maybe I missed that.

Tom Tsang – ONC – Medical Director
....

Judy Faulkner – Epic Systems – Founder
Excuse me?

Tom Tsang – ONC – Medical Director
It's by the individual.

Judy Faulkner – Epic Systems – Founder
Yes, okay, but what if you're a family practitioner and you've seen both?

Tom Tsang – ONC – Medical Director
... pick one or the other.

Judy Faulkner – Epic Systems – Founder
You have to pick the adult. That's the first one.

Tom Tsang – ONC – Medical Director
The measures have very, very specific specifications in terms of numerators and denominators as defined by measure developers. So you're going to have to do those and then if you have a pediatric population there's an additional 38 measures from which to choose from and there are a few pediatric measures that you can choose.

Judy Faulkner – Epic Systems – Founder
So if you are a family practitioner seeing adults and children you'd do both then, the adults and the children?

Tom Tsang – ONC – Medical Director
You'd have the option.

Judy Faulkner – Epic Systems – Founder
That was the option that worried me, okay.

Tom Tsang – ONC – Medical Director
You're talking about the specific measure?

Judy Faulkner – Epic Systems – Founder
The specific individual.

Tom Tsang – ONC – Medical Director
The measure specs are extremely specific in terms of numerator and denominator and the population defined.

Judy Faulkner – Epic Systems – Founder
Then let me just ask that question then. If they're extremely specific what is your valuation? If you are a family practitioner and you see half adults and half kids, will you do both measures?

Tom Tsang – ONC – Medical Director
You're going to have to pick one or the other.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Gayle?

Gayle Harrell – Florida – House of Representatives
I wanted to go back. I had another question that I did want to ask that deals with when you are going to aggregate your data across care settings. In the care coordination model that we're looking to move to, what will be happening when you don't have the ability to do that? Or in different sections of the country whether or not the local HIE is up and running by stage two and if you don't have the ability it's going to be inconsistency across geographical areas as whether or not that care coordination will be possible. How are you going to deal with that in your measures?

Tom Tsang – ONC – Medical Director
I think that's the reason it's on the list of policy issues for the group to discuss is because it's difficult and the scope of implementation is unclear. So whether we're able to use those kinds of measures in stage two or stage three or whether they become a menu option that is available to some but not to others optionally, or an alternate, those are questions we haven't really weighed through yet. But they're exactly right for us to take up.

David Lansky – Pacific Business Group on Health – President & CEO
I think everyone has to remember that the discussion doesn't end today here. I think certainly it's going to be an involving discussion where input is still going to be needed from the other workgroups from both the Standards front and from the HIT Policy Committee. I think those are critical discussions that we need to contend with.

Gayle Harrell – Florida – House of Representatives
I think I would agree with you, and it's going to be inconsistent as we move forward, at least in the near term. I also wanted to make sure, I want to again put in a plug on the specialty measures and make sure that we do move forward with those. That would be very, I would think, extremely important.

David Lansky – Pacific Business Group on Health – President & CEO
We have 69 ... already.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Marc?

Marc Probst – Intermountain Healthcare – CIO
Just a quick comment and a question on what Neil was talking about. I do think an outcomes driven process for looking at measures, it would be helpful to have that conversation at some point. I know you do talk about it, so I'm not saying this is revolutionary thinking, but there is a diminishing return, I think, even on how we use quality measures. If we put too much information out there or too many measures we don't get the change in behavior that we're looking for. So that's just a comment.

Quickly on the settings of care, are there more columns in the spreadsheet? It seems to me that some of the measures are more relevant to eligible providers than maybe hospitals, and where is that brought out? Maybe it isn't in this particular piece. I guess that was a question.

David Lansky – Pacific Business Group on Health – President & CEO
It's not brought out in this particular piece. There is a listing in the full elaboration from the work we did prior to this distillation of all the hospital specific measures versus the EP measures. Maybe we need to make that a little bit more visible, which are in the hospital queue.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Paul?

Paul Egerman – Software Entrepreneur
This is a specific question on timing, since that's probably the number one comments we get back. So this is a perspective from the Meaningful Use Workgroup. You talk about the latter half of this year states should measure ... specifications to be defined and put out for public comment. Can you explain how that

works in juxtaposition to the NPRM process that CMS would be going through for stage two and how should we look at that from the Meaningful Use Workgroup, or from the Policy Committee?

David Lansky – Pacific Business Group on Health – President & CEO
As the harmonization process plays out and as we initiate the procurement process, I think we're going to have to have a very, very solid and very specific numerator and denominators for each measure to really put out for public comment during, I guess I would say the late fall of this year. While that process is going on, I think we're going to have this parallel process of looking at the feasibility, looking at the evidence, looking at the standards process. With the input from the public based on the NPRM, I think we're going to then either scale back or perhaps re-think whether those measures will be suitable for stage two.

Paul Egerman – Software Entrepreneur
So your thought is that the output of this group would go into the presumptive December NPRM for stage two coming from CMS?

David Lansky – Pacific Business Group on Health – President & CEO
I think it's going to be one input into that process, and it has to be balanced with what CMS is doing, what the other federal agencies need. As we talk about this harmonization process we really have to think about what the community centers need, what the CDC needs in terms of public reporting, what … needs in terms of their initiatives, especially the National Quality Strategy Initiative. So there's a lot of juggling that needs to take place.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Larry?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
I guess we're all having related thoughts. I have a sense listening to this that there's some really great thought going into where do we want to go, some things that we feel pretty visionary in terms of the multi-source bringing it together and looking at data longitudinally, which I think are absolutely right. I'm also hearing recognition of how do we balance that longer view with what we can actually get accomplished to put into stage two so that we actually have measures that have been through a full vetting process that are well tested that we've got validity across settings and all that stuff. I really want to encourage both that head in the clouds but feet on the ground stuff that's going on and that we continue to work on both of those fronts. Because we really need the strategic vision clear so people can start to head towards that, but also very concrete things that everyone is solid about and we don't get into arguments about the data's no good. We have to get beyond that. We have to get people going, yes, the data's good, the measures are good, and we understand how we got them.

Also, I guess an encouragement that as we develop measures and there's a lot of reason to have ... specific measures, that we be really careful that we don't get measures that sound like they're the same thing when they're not the same thing. So we could be looking at an outcome in one setting and an outcome in another setting that's measuring the same general thing and it gets called something specific. So we might talk about, I don't know, blood pressure control or glucose control and wind up with well the way the docs are reporting it is different from the way the hospitals are reporting it, and it's different from how other non-incentivized providers are reporting it. We actually need at a policy level to start to say which care settings are right for delivering particular services and for managing a condition, and if we've got measures that everybody has tweaked to their setting, we lose that ability. So whether it's through how we collect the atomic data or how we actually start to define measures that we start to look at measures that actually hold up in multiple settings.

David Lansky – Pacific Business Group on Health – President & CEO
I think one of our obligations is really looking at during the testing validation phase, to look at feasibility, reliability, and validity of these measures. We're working very closely with CMS looking at the testing and validation methodology in all of these measures. I think that's going to be the critical part where we're going to learn the best practices in terms of implementation, whether it really works in a provider setting.

We're trying to develop a process where we're going to have a wide range of providers from ECHCs to small practices to hospitals using a wide range of EHRs. I think that's going to be guiding and informing us on a lot of the issues that you talked about.

David Blumenthal – Department of HHS – National Coordinator for Health IT
We're coming to the end of this segment of discussion. It's been a very, very fruitful discussion, very wise. I want to make one contextual point as we move forward. There is no place in the federal government, I don't know if there's any place in the private sector, I'm sure there are places in the private sector, but there's no place in the federal government which is focusing on harnessing the power of electronic technologies to quality measurements except for this group. So we have taken it on, the Office of the National Coordinator has taken it on as a task and a mission and has put it on your shoulders to help us to plan for that future, to plan for the future when information in electronic form will be far more robust and cheaper and easier to get.

So if you all feel like you are tiptoeing out on the ledge, you are. But there are plenty of other groups and forces that will be glad to hold you back and kind of say stay with the old thing you've been doing because we know that that works, or it's simple and everyone understands it and there's consensus around it. So even though there are issues of timing, even though there are issues of electronic exchange that may or may not be there, even though there are all kinds of practical questions, I would urge you to keep pushing the frontier. Because the system will catch up with us eventually and the work done here will be valuable when the system catch up catches up. If we don't develop the measures and put them in the system and put them there for use at a later time, they will be less likely to be available when they're needed.

Having said that, I want to come back to the question of what the purpose of this is in terms of the meaningful use framework. We are in some sense going to become, the meaningful use framework will become the raw material for the work of private and public providers and payers whose goal it is to improve quality through systemic change. It's not going to happen necessarily because of the measures we collect. But the measures we collect will make it possible for other leaders and other influences to produce change. It is true that reporting measures may or may not change provider behavior, I think it sometimes does, sometimes it doesn't. But if you have the measures you can then add incentives so that Neil's physicians' compensation depends on their improvement of their measures rather than just whether or not they happen to read the measures. They'll start reading them as soon as their bonus or their annual compensation changes with those measures.

I think that even then you'll have to be parsimonious because they can't do everything at once and you need to support them and help them make the changes. Some of the changes are not under their control exclusively, so all those things are true, but unless the measures are there it's a lot harder to bonus them for improving them. I think this is sort of a foundation of raw material for all kinds of positive use. We are the only group that I'm aware of in the federal government who has developed saying this is what the record can do, this is the kind of new measures you could develop, this is how you would develop them, these are the specifications. These are the standards, and now they're ready to use them or not when you're ready to use them.

David Lansky – Pacific Business Group on Health – President & CEO
David, can I just add a comment. I think we have great appreciation for the dozens and hundreds of volunteers and commenters who have given us fodder for that foundation building these last few months. I think we are unique, I guess, in the federal program of being the funnel which is capturing all the expertise out there in the country and bringing it to this room so that we can begin to get a broad national discussion and consensus around what those tools could be. I know in our context and my day job in the private sector there's a lot of interest in taking advantage of these emerging measures that are coming through our process to use in the other recognition programs, payment programs, quality improvement programs that we're supporting. So it is under a lens by a lot of people and it's also the channel through which a lot of expertise is being collated. So it's a unique opportunity we have. I do think I'd like to get the support of this group today to formally endorse where we are in the process and take it forward to the next couple of steps that we've outlined.

David Blumenthal – Department of HHS – National Coordinator for Health IT
I guess it's a sense of the committee that you should continue this work, that we appreciate it and value it and definitely you should continue it. Okay, go away with our blessing.

David Lansky – Pacific Business Group on Health – President & CEO
Thank you very much.

David Blumenthal – Department of HHS – National Coordinator for Health IT
We're going to change the guard here and change our focus from quality to privacy and security, our hard working, persistent, courageous, Privacy and Security Tiger Team is going to tell us where they are on their work on authentication of users.

Paul Egerman – Software Entrepreneur
Thanks for that kind and interesting introduction. I'm here with my colleague, Deven McGraw. We are going to talk about user authentication. What's going to happen is I'm first going to take you through some of the technical jargon and then she'll take you through the law. So this is going to be a fascinating discussion.

First, I want to explain what we are addressing. The topic that we have is "Authentication of EHR Users." I want to explain first what an EHR user is and then I'm going to explain what authentication is. An EHR user is somebody who uses the electronic health record system. It's a physician or a nurse or a healthcare professional. It can be an administrative person or an executive. It's sort of like everybody except patients. It's not a patient. In other settings, you would call these people employees. That doesn't work in healthcare. This slide set has the word "staff." That doesn't quite work either. But these are people who have to use the record in order to treat or process patients.

We are also initially looking at a use case where people are accessing this system across a network such as the Internet, and the best way to think about this is that they're doing it remotely. So this could be a physician or an administrative person operating from home on a laptop. It could be somebody operating with a mobile device. That's our initial use case. We're not talking about people inside the four walls of the enterprise, although we will be discussing that in a minute. That's the concept of an EHR user.

Then to quickly walk you through the terminology and make sure we explain what is authentication, you see this slide; this has four concepts in it. The first one is this concept of identity. That's who you are. The next concept is an identifier and lists down in very small print the kinds of things that are identifiers, which is something you have, something you know, or perhaps something unique about you that's written in really small print that's not intended to be like a security capability because you can't read it, but it's effective in that way. So the concept of something that you know is like a password, something you have is like a card, and something that's unique about you could be your fingerprint or something for biometrics. So that's an identifier. What's authentication? Authentication is the way you prove who you are. You use one or more of those things and you say this is who I am to the computer.

There's a fourth concept that's called authorization, and that's not something that we'll be talking about today. But what authorization is, is after I prove to the computer who I am what am I allowed to do? So, Paul Tang authenticates himself in the computer system, and the computer says, oh, Dr. Tang, you're a physician, you can write prescriptions. Maybe I authenticate myself in the computer and it says, oh, Paul Egerman you're an appointment clerk. You can make appointments, but you can't write prescriptions. So that's authorization. But we're looking at authentication, which is just how you get into that front door to get started with the system. So again to go through the terminology, authentication is verification that the person or entity seeking to access the electronic system and the protected health information is the one that he or she claims to be. There's this other concept called token, and that's how you identify yourself. The token could be your secret password. It could be a physical document, like a card with a magnetic stripe on it. It could be a biometric.

Then you have the expression "two factor authentication" that you'll hear a lot of, and what's two factors? Well, it's really two of these things. While that may seem simple, when you get into it it's actually very complicated. So there are two factors and some people say it's two different factors, one thing that you know or one thing that you have may be two factor authentication.

That's the basic terminology. Deven's going to tell you a little bit about the background and the law.

Deven McGraw – Center for Democracy & Technology – Director
Thanks a lot, Paul. I wanted to make the comment that for maybe the first time, we are presenting before lunch. I don't know what we did to deserve that, but I thought it was a momentous occasion that I wanted to remark on.

Paul Egerman – Software Entrepreneur
The question is did we do something right or wrong?

Deven McGraw – Center for Democracy & Technology – Director
I don't know. That's a good question.

M
Are you really the Privacy and Security group? Maybe you weren't properly authenticated.

Deven McGraw – Center for Democracy & Technology – Director
We didn't present our second token. As is always the case, we desire as a tiger team, and I think as a Policy Committee, to put together really a comprehensive framework of policies. But you can't start with a universe that big. You have to slice and dice it topic by topic. So we're diving into the topic of policy for user authentication and I think it's helpful to keep a couple of things in mind. One is that we don't expect authentication to be the linchpin of security. It's really just one element of it. We assume in fact that the identity piece, the diagram that we were on, first, you have to prove who you are, the authentication is proving who you are, but who are you has to be established. We assume that these provider entities have actually issued credentials and in fact that the entity is following the security rule and has put in place administrative, technical and physical safeguards.

Again, authorization is one component of security but it's not the be-all and end-all. We want to talk a little bit about what does the HIPAA security rule says about authentication in particular. As you'll see, we have just really summarized it here, but entities covered under HIPAA really do have to protect against any reasonably anticipated users' disclosures of electronic protected health information that are not permitted or required under the privacy rule. So therefore they have to implement procedures to verify that a person or an entity seeking access to the … that they have stewardship over is really the one claimed. It does not mandate any particular implementation framework, and it doesn't specify authentication options, assurance levels, or verification types. So it does set requirements for authentication processes and practices and procedures, but doesn't say they have to be at a certain level or they have to include two factors, as we'll talk about in a minute. That's really the baseline that we're working under.

A couple of other things that we looked to as a tiger team in having these discussions are a document that was put out by NIST which specifically applies to authentication within the federal government but has been used by a lot of other private sector initiatives in building authentication frameworks. What's relevant I think from this slide, we don't want to get into too much of the details, but what NIST has done is to set different levels of assurance between one and four that are aligned with essentially what would be the impact if there was an error in authentication. It ranges from low impact if there was an error, which is level one, all the way up to a high level of impact if it was a level four. The most relevant application of this document or use of this document in the healthcare sector is really the interim final rule that came out for the prescription of controlled substances that came out of the DEA, which actually came out in June 2010 but it's an interim final so there may likely be a final, final rule. But it is in fact a final rule and entities are in the process of modifying systems in order to comply with it.

They landed on level three assurance, which is a relatively high degree of confidence that the individual is who they say they are. Which isn't so surprising if you think about the level of sensitivity of the data in a prescription for a controlled substance and probably also the law enforcement needs that are at stake with respect to making sure that these prescriptions are being prescribed appropriately. It's modeled after this level three, and so therefore, it requires what's called "two factor authentication." As Paul explained in the beginning, the factors for identity are something you have, something you know, something that is unique about you. What's relevant in the DEA context and also in a strict application of that NIST framework is the two of them can't be in one category, you have to pick something you know and then either something you have or something that is unique about you. So in the case of the DEA rule, it does require two factor authentication and you get to pick two from the list that's here, some type of hard token, a knowledge token, which a password is a knowledge token, or a biometric. Then of course there are also some stringent credentialing or identity proofing requirements associated with that.

In trying to talk about this issue and where we want to land from a policy standpoint, at least beginning with the use case of remote access, I think in general the team really felt as though remote access raised some heightened security risks for access to identifiable health information. In looking at the NIST assurance levels in the document that I just shared a snapshot with you on, people were most comfortable with landing on a minimum level of three, given that health data, even if you're not talking about a controlled substance, is sensitive data. So that's really a high degree of confidence that the individual who is seeking access to the data is, in fact, who they claim to be.

Generally, the other sense of the tiger team was that a single factor of authentication, a mere log-in or a password would probably not be enough. Certainly in the NIST framework that we shared with you when it's at level three it is multi-factor authentication that is required, so at least two, so something you know and something you have, if you're strictly going by the NIST framework. But where we have, at least to date, have struggled to reach some consensus is whether we want to set a baseline policy requirement regarding which factors ought to be required.

Now I'm going to turn it over to Paul to walk through some of the considerations that we've gone through and some of the issues that have come up in our conversation. Our hope is during this Policy Committee meeting that we can get some input from you before we finalize these, which should also help smooth the way for the recommendations being generally acceptable when we land on them.

Paul Egerman – Software Entrepreneur

Thanks, Deven. Basically, we have some questions as we look at this. If you think about the whole concept of what we're saying, you have to balance, let's call it the "risk with utility," is the way to think about it. When we look at it from a risk standpoint, it was easy for the tiger team to say level three. It just came very easy, level three, that's what DEA is using for controlled substances, so you can make an argument, well, gee, even though controlled substances has a lot of security issues with them, why not take that single approach for everything. That would be simple, level three. So that was what we said. But then we started to think about that and we said, well, maybe that's a problem when we think about the issue of utility, in terms of how useful this is going to be. Because one of the challenges you have, of course, is we want to get people, we want to get physicians to use the system. We don't want to make it hard for them to use the system. So there's some concern that if we make it hard for them to use the system it's going to be self-defeating. There's also concern about the DEA approaches, because it hasn't gotten a lot of traction yet. In other words, it's not really being used. Maybe it's too high a standard, so we don't know. We have some questions here.

The first one is, well, should we do two factor authentication? Again remember this is remote EHR users, this is outside of the four walls. Should we do that? Or, should we try to be a little bit more flexible, so one is we could endorse the DEA approach. We could actually try to use an approach similar to banks, which is not quite level three, where banks say there's two things you know, you have to know your user name and password, but you have to know the middle name of your great grandfather's uncle or something. So when you do that sometimes those things are kind of annoying. What was the name of the elementary school you went to, and you say Field School and it says no. You say Field Elementary School, and it says no. You say Field, and it says sorry, and it goes on to a different question. So

sometimes, it can be very annoying. But that would be an approach that you can take. Or you can say maybe what we're going to do is think that the baseline is level three, but we're going to wait to see how DEA pans out. If that works out well we'll use it. We'll give it a chance. That's one set of questions.

Another concept that has been brought forward is to allow a single factor but to focus on what's called "rigorous" password management, which has been suggested by MITRE Corporation. Some of the members of the tiger team were not excited by this because this is the kind of thing where they make you change your passwords every ten or twenty minutes or something. It says oh, you can't use that password because you used it six months ago. Those are also things that sometimes annoy people. But that would be another approach.

Then the third question is ... well maybe one size should fit all, maybe we should try to look at this from a risk standpoint and just choose the ... for DEA, as some things are riskier than others. So maybe what we should do is rather than set a floor and try to put that into the regulations or something, we just should issue some guidance in best practices. That would be a solution. That sounds very appealing, except when you start talking about some of these discussions. Like Larry raised the issue of PCAST, and you look at information exchange so you have this concept of NW-HIN and a nationwide network, you think it's like the air traffic controller system, maybe the network's only as good as the weakest link. Maybe that's not the right approach. Or maybe that's the right approach for now, but later on we need to raise the bar.

That's the issue that we're wrestling with is how do we assess this difference between risk and utility? If we do it at risk and we say level three, that has definite disadvantages. It makes it a little bit harder from a utility standpoint. Should we go that far right now? There's another question about inside the four walls, but maybe I should pause right here and see if people have any comments or feedback, because that's actually what we're looking for.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Thank you very much. I think that is the clearest presentation of this issue I've ever heard.

Deven McGraw – Center for Democracy & Technology – Director
We must have left something out.

Paul Egerman – Software Entrepreneur
That's how we got to be before lunch.

David Blumenthal – Department of HHS – National Coordinator for Health IT
It's before lunch, that's why. I'm not sure whether you're clearer or we're more awake. Why don't we just start with Tony and move around the table?

Tony Trenkle – CMS – Director of OESS
I agree with you. That was a very clear presentation. Just a couple things I wanted to mention. Number one is the whole issue of risk versus usability is obviously a big trade-off. I think sometimes, as you mentioned, with a 20 minute password or whatever, sometimes as you attempt to minimize risk you actually can increase the risk because you make it so difficult from a usability standpoint that people look at ways to get around the types of passwords and other types of controls you put on there. So the question I wanted to ask is have you thought about in terms of compensating controls to help mitigate some of that risk what some of the advantages that EHRs bring in terms of audit trails and other types of things that you can do. Certainly that's one of the areas that we've been looking at in CMS in terms of fraud control and other types of things, so I'm wondering if as you look at trade-offs what are your thoughts there.

The other is, we've had a number of talks with vendors and I know there's a lot more work that's being done in two factor that goes beyond some of the areas that the DEA looked at in terms of hard token and biometrics. But they've looked at other types of multiple factor authentication, and if you look at the

confidence levels that they have behind their verification engines, there's a lot of thought being applied to that, which could help in the usability area. But I didn't know if you had any thoughts on those two areas.

Paul Egerman – Software Entrepreneur
Those are both great comments, Tony. On the first issue that the effort might actually harm security, that first part of your comment is really an excellent comment, because one of the things I've seen a lot is sometimes as you look at these systems in isolation the users frequently have to sign on to multiple systems. This is particularly true in a lot of settings with a nursing staff, where they have to sign on to an EHR system and a medication administration system and something else, and there's so many different sign-ons that they just take the names and passwords right to the device, because it's so much easier. I actually saw somebody who had a PDA, a handheld device, who worked actually at Brigham, at Beth Israel, and at Harvard Vanguard, three large healthcare organizations in Boston. She had written all of her sign-on information on the back of her PDA, so it wasn't even internal; it was just written there because it was just too hard for her. She went to every place once a week and it was just a difficult thing.

On the issue of the technology changes, you're right about that. There are some things that happen, especially when they do two factor authentication and devices that have a lot of potential, especially for multiple devices, that could help a lot. It's more there than in the biometrics side. So we have looked at that and that's a possibility. I don't know if you want to comment on it, Deven.

Deven McGraw – Center for Democracy & Technology – Director
I think the other thing that occurs to me with your comment, a couple of things. One is, you mentioned audit trails and other security functionalities and parts of a security program that are really tied in pretty closely to authentication in terms of making sure that the person who is authorized to access the record is the one accessing them, and I couldn't agree more. We just made some summary statements at the front about assuming that people are complying with the security rules, but I think we could probably emphasize the ones that are a little more relevant to authentication and think about how those all knit together, if that makes any sense, in terms of trying to slice and dice the universe. I think we do tend to get very narrowly focused on the one thing that's in front of us, but I think it's very interrelated to some of these other security aspects.

In terms of what some other initiatives are doing in terms of suggesting other factors, I think the challenge for us is to think about what a policy recommendation might look like that doesn't narrowly focus necessarily on one technical solution. But that allows maybe for a little bit of market innovation and for entities to choose the solution that works best for them.

Tony Trenkle – CMS – Director of OESS
Yes, that was my concern with DEA is it did narrow it to more of a technical solution without taking the fact that technological innovation that's going on that allows you to achieve the same types of risk management without the onerous usability problems.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Gayle?

Gayle Harrell – Florida – House of Representatives
I know everybody's tired of hearing me on my privacy and security kick, but I've got to really chime in again and say how important it is to make sure we have the public trust in how we go forward in this. The authentication element is so critical to that when you have breaches and fines at Mass General recently, this just raises the public's awareness once again of vulnerabilities that are out there. We have got to make sure that we do everything possible to ensure the public trust in where we're going. I happen to believe that two factor authentication is essential. I think the DEA, as we're moving forward, they have had perhaps part of their issues have been lack of education of physicians and providers out there who have the ability to ePrescribe and now ePrescribe controlled substances. So there are many things that go on and it's not just one element in why a system perhaps is not being as utilized as perhaps we think it might be. So we need to look at the whole thing.

I'm part of the National Foundation of Women Legislators and we were at a conference. I was distressed, having been involved for so many years in health IT and so passionate about it, distressed to see the lack of understanding even among state legislators as to what the abilities of electronic health records would be in empowering their states to save money in Medicaid bills and whatever, and their extreme fear of what we're doing in privacy and security. So I think there needs to be an education component for the public as well as to whatever the decisions are that come out of this. I happen to support the two factor authentication, but wherever we go the public needs to know what the process is, what the very basic foundational stones for privacy and security are, and I think we need to make sure that that happens along the whole road, whatever this decision is. But I think we need to err on the side of caution as opposed to utility.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Judy?

Judy Faulkner – Epic Systems – Founder
First of all, I thought it was very good. Thank you. I like Deven's innovation that we need to leave it open enough so that we have innovation. I like Paul's comments about people writing things down, because once the codes get complex and change frequently you see them on Post-Its on the screens. In particular I want to support Tony's comments on the risk trade-offs. Where I see the problem mostly with remote is when the physicians are on call, because that's when they may have critical decisions to make very quickly, and access to the information rapidly is going to be, I think, perhaps the biggest risk of a bad trade-off if they can't get to that information quickly. So I just wanted to throw out that. Perhaps there's a way that the systems can recognize, and there should be, who's assigned to being on call and then have a different level of security for the on call physicians, to make it quicker, because you already know. You have almost one level of authentication, you know who they are, so that we don't harm people by not responding quickly enough to an emergency situation.

David Blumenthal – Department of HHS – National Coordinator for Health IT
David?

David Lansky – Pacific Business Group on Health – President & CEO
I share everyone's appreciation for the report, thanks, and the education of it. I have three quick points. One, I think it's always been frustrating in these discussions not to feel like there was enough evidence of actual rates of risk error or delay in access, as Judy just described, from the different methodologies. I think as we go forward it may be worth creating a database of evidence essentially, so that as innovation continues to occur, we can evaluate novel approaches against existing practice and decide whether we're getting a benefit and a risk benefit trade-off. But I think as our discussion analysis continues I'd appreciate seeing whatever evidence the banking industry or others have that give us some sense of how much play is there in these different choices that we're considering.

The second point, I don't think you spoke specifically to the identity proofing question of initial identity management. I know ... another one of these weakest link questions, and that takes me to my third question, which is about whether the issue of patient access to their own record is fundamentally different from the authorized user remote access question, or is it just really a different role and associated authorizations with a different role. Because there are many staff functions of various kinds of customer support and remote users and appointment schedulers and so on, who from a security and prior clearance point of view, or licensing or other expectations of credentialing, don't have any special distinction from a consumer except that an institution has hired them and put them on some basis.

So the question identity proofing becomes important as we play out the role authorization analysis, which is not part of today's discussion but it's associated with it, and obviously ultimately we want to have increased patient access that many of our recommendations have focused on. I think having a continuum of user types and associating the authentication requirements, identify proofing, and authentication requirements with that continuum would give us a framework that as we continue to look at different types of users and different use cases we can make these assessments about which of these criteria should be deployed.

Paul Egerman – Software Entrepreneur
Those are great comments. I wanted to respond to your comment about patient or consumer access. First, that's not really what we've addressed so far. That is hopefully our next topic. We had wanted to spend the month of March talking about patient or consumer access, but patient and consumer access is a bit different, in my opinion, because as you set it up, in theory at least the patient only has access to one record and also in theory has no, or limited ability, to change the record. So you gave an example of an appointment clerk, but an appointment clerk, at least in theory, has perhaps access to hundreds of records and can make changes. If you think about clinical data, arguably two of the most important pieces of clinical data are patient gender and date of birth, and an appointment clerk enters that data. That's just an observation.

The observation about evidence is a very interesting issue. I don't know what evidence exists, although a lot of these things are designed around what it would take for somebody to break through. In other words, strong passwords and some of the password rules that are really designed so that you couldn't in effect have a little program that signs on and starts with the number one and keeps iterating through passwords until it finds one that works.

Judy?

Judy Faulkner – Epic Systems – Founder
On the evidence, I have never heard among our customers of any breakage of any of the codes, just as a comment.

M
A couple of points: First, many of the Western European countries and other countries have dealt with and arrived at a solution to these identification authentication issues. They may not be transferable, but they'd be worth at least our being familiar with. I think our staff should be able to support you in getting familiar with those. Some of them involve physicians having a token, so that's just point number one.

Point number two, the question of utility or convenience is not a fixed property of thermodynamics, not a physical law. People will put up with inconvenience if they see the value in putting up with it and if they're convinced that the trouble is worth it, for whatever purpose. I don't think we have spoken sufficiently to the provider community, many of whom, frankly, are just completely naïve to this discussion. So it never occurred to them that they would need security to access their own electronic health records because they're their electronic health records, right, so who else could have access to that and why should they need any passwords at all.

I happened to be talking yesterday with the deputy administrator of the CMS for program integrity and he pointed out to me that there is a huge issue for physicians of identity theft. Scammers steal physician identities so they can set up illegal building operations, and once that happens, it is a devastating event to clarify it for the physician to straighten it out. One utility for physicians, one reason to put up with that inconvenience that I don't think we've made clear, is the ability to protect themselves against identity theft and misuse of their identity. I think as we talk about identity proofing and authentication, that's another rationale for putting up with inconvenience, that we may want to message better to the provider audience.

The third point I would make is that for years I used two factor authentication in the form of a password and a randomly generated number, a token. I frankly just stopped noticing it after a few months. I don't think that there is a fundamental obstacle here. I think it's a behavioral issue. Though I do believe that's a real issue and one that requires persuasion and management to overcome.

Paul?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
A couple topics: One is, thanks for tackling the patient authentication this coming month, because I think that's actually something we're facing right now, and the numbers are huge of course in terms of the

number of patients. The risk, even though you can only access one record at a time, you can cause that record to be, let's say, put out to another PHR instantly and you only need that ten minute access, and so other things that come back, like an e-mail saying hey, somebody's changed it, it may be too late. In other words, there's a real risk to that individual, and so thanks for tackling that. I think it's going to be very important.

The second is just, against your questions that are raised, to offer some experience in the field. It echoes a lot of the things that have been said. Every organization that I know uses two factor authentication when you're remote from the campus, versus just a password on campus, and with thousands of physicians, to speak to what David said, that has not been a problem. So there are a few people who voiced their concerns but I think it's a combination of explaining the value both to the patients and to the physician in terms of whether stealing your identity or writing scripts against controlled substances, people are concerned. I would say the experience from the field from just the thousands of physicians that I'm aware of has not been a problem, so that would reinforce what your workgroup thought initially. And everybody else's, the complex password I think everybody's speaking from ... one but I think the fact that everybody's ... one themselves writes them down shows that the bottom of the iceberg is probably huge too. So I think that turns out to be a self-defeating program.

The final one, if it comes back on the screen, has to do with let everybody follow their own practice or best practice. We had a large meeting in California with a lot of health groups that are doing the information exchange, and recognize the diversity of the confidentiality policies and the ability to exchange and realize how crippling that is, it goes back to what you said, Paul, that it's really the lowest common denominator. Whoever has the least protected policies, essentially all information can and potentially will flow to that area to leak out, so I think that would also speak against us saying everybody on their own.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Larry?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
I feel a little bit of déjà vu. I was in a very similar meeting at work earlier this week, because we were revisiting what we require of our physicians to provide them remote access, and historically we've required a token. The first thing we got as a response years ago when we asked, how do you like our new security remote access, isn't it great? You saw all these applications. One of the docs held up his keychain with a fistful of tokens and said, no, every place I go to requires that I have a token and it's a different token.

So perhaps one thing to think about as we go into this at a policy level is how can we start into a pathway that's going to lead us to fewer methods that are more broadly usable, so I can have my identity that I can prove somehow that this is me. That that lets me get into all the different places I need to get into without requiring that each place have their own method that has variations. Strong passwords, great, okay, but each place has slightly different variations on a strong password so I can't make them the same if I wanted to because – anyway, we don't need to get into that. So we said, no, sorry, you've got to use your token. The doc said, great, instead of using remote access I'll just call in and have a conversation with the staff and do my orders verbal. Thank you very much for your increased security.

Now we're looking at less invasive ways to provide a second factor, so using digital certificates embedded in a known device, and those kinds of approaches. What can we do to increase the utility and maintain the risk level but decrease the threshold to the user, so technical solutions that might help that. I guess I'm concerned because when I had these conversations at informal meetings, like I'm at an HIE meeting and I ask around the table, okay, well, in all the organizations we provide remote access, what levels of access do people provide? I don't have Paul Tang's experience. My experience is probably a third of the organizations have a single factor authentication process and that their users come back and say, well, I go to my bank account and that just requires user ID and password, so that's their expectation of what's necessary.

I think we actually have in the world a mix of experience. But I'm also hearing back from them sort of a level of sophistication in the answer of the level of authentication tied to the authorization. What is it you're going to do? Are you accessing a single record at a time and it's read-only? Are you accessing multiple records? But you can't extract the data. So looking at the scope of things, so what's the organizational risk if you do something bad? Are you going to publish 10,000 patients' records that are suddenly going to be at risk, or one record is at risk? So I'm looking to bring some more complexity to this.

I'm also reminded of—that's like a year and a half ago at one of the hearings we had a forensics guy from Verizon speaking about their experience of what actually are the risks. While I thought his contribution was great, I also thought it was really narrow, that there was just a certain kind of risk that he was being brought in to assess. But it might actually be useful to get more field experience of when people have breaches, what actually is the cause of the breach. Is it a technical breach? Is it a human process breach? What actually are the causes? So that when we put safeguards in place, we're actually addressing the things that are causing problems not just the things that are technically sophisticated.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Marc?

Marc Probst – Intermountain Healthcare – CIO
Paul and Deven, great work. On the first question on whether we should require two factor authentication, I don't believe we should require that. I think what we're looking for, or what I'm looking for, is a level of assurance. HIPAA's got laws and regulations and requirements and penalties associated with that as to what will happen if we don't protect the data, so we want a level of assurance. That could be two factor authentication, and in fact, to Paul's point, that's what we would use, but I don't know that in the future that has to be the way to do it. So if there are ways of doing it, there are technologies now that I can go in and I can look at the traits of how a physician uses our system and identify whether that's the right person or not and whether they should be in there. So I think this technology is growing at such a rapid rate we should be setting a level of assurance we're going to keep the patient's data safe.

How we do that, and I guess I am differing a little with what Paul said at the end and the answer to your third question, I think we should be able to, it's going to vary by circumstance. It's going to vary by what data, as Larry suggested, that clinician is going to go in and look at, or that staff member's going to look at, and certainly I would have a different requirement for a staff member probably then I would a physician, but I think it is going to vary. I'm just a little hesitant to require a specific approach when the technology's changing so rapidly that I could have a single factor authentication approach that may be as good or better than a two factor authentication approach. I think what we're getting at is we want to protect patient data, and again, I'll go back to again I think HIPAA does that.

Paul Egerman – Software Entrepreneur
The view, Marc, we're looking at remote access.

Marc Probst – Intermountain Healthcare – CIO
I understand that.

Paul Egerman – Software Entrepreneur
You understand that, okay. So your advice would be to somehow establish it as a concept of a level of assurance, that you've got to do two factor or you've got to do something that gives you the same equivalent level of assurance, is that what you're saying?

Marc Probst – Intermountain Healthcare – CIO
Correct. So I'm not, and Deven is, but I'm not an expert on HIPAA, but I understand HIPAA does – all right, nor is she.

Deven McGraw – Center for Democracy & Technology – Director
I always get a little nervous to be claimed an expert on anything.

Marc Probst – Intermountain Healthcare – CIO
But it seems to me it sets down a certain requirement of what needs to be done. I just hesitate in requiring an approach on how to do that when technology is changing so rapidly.

Paul Egerman – Software Entrepreneur
So that's like two factor with a little bit of wiggle room.

Marc Probst – Intermountain Healthcare – CIO
No, I think it's a level of assurance.

Paul Egerman – Software Entrepreneur
A level of assurance, okay.

Marc Probst – Intermountain Healthcare – CIO
Yes, two factor can be broken as well, and two factor can be a problem, as Larry suggested, when you've got all these different tokens that people have to carry around. It comes to that diminishing capability because it's so complex in what people are doing.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Go ahead, ...

Marc Probst – Intermountain Healthcare – CIO
... two ....

M
... technique for reaching a certain level of assurance.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Judy?

Judy Faulkner – Epic Systems – Founder
I have a question, and that is, if you use biometrics, is that really strong? In other words, I went through customs recently and they take a photo of you as they look at your photo. If you can be using face recognition technology, is that by itself strong enough?

M
....

Paul Egerman – Software Entrepreneur
That was David's question. I think we need more on that.

M
....

Paul Egerman – Software Entrepreneur
It's a great question. If I understand it right, and tell me if I've got this right, Deven, NIST doesn't really accept biometrics but the DEA does for—

Judy Faulkner – Epic Systems – Founder
But then you just need one. I have to say I'm me and my picture looks like me.

Paul Egerman – Software Entrepreneur
That's right. There are some controversies around biometrics.

Judy Faulkner – Epic Systems – Founder

Yes.

Deven McGraw – Center for Democracy & Technology – Director
You can't directly use a biometric under NIST. It can be supportive of another element of identity.

Judy Faulkner – Epic Systems – Founder
But is there a good reason why not?

Deven McGraw – Center for Democracy & Technology – Director
Well, I don't know. But I think it gets to the question of whether at a policy level we want to say that it's okay to do one factor as long as you are confident that you reach a high degree of confidence that you've authenticated the people who are accessing our system remotely. Versus saying thou shalt use biometrics or thou shalt not use biometrics. We certainly have not delved into that in any detail, and I don't think actually it's a policy matter that we would want to do that.

Judy Faulkner – Epic Systems – Founder
Why not? Because if in fact biometrics is determined to be a strong single factor, why not?

Deven McGraw – Center for Democracy & Technology – Director
Then the policy would be, you can use single factor as long as it's biometric. I'm just trying to translate what—

Judy Faulkner – Epic Systems – Founder
I'm wondering if that is a reasonable thing ... if we find that biometrics is a very strong thing, certainly stronger than putting in where I was born, where lots of people know as here's my password, here's where I was born, that seems less strong than here's face recognition or here's my hand print.

Deven McGraw – Center for Democracy & Technology – Director
We can do a little digging, but I think it is exactly the set of circumstances that, I'm trying to remember who raised it. I don't know that there's a strong objective evidence base out there one way or the other about the use of biometrics. Certainly I've talked to many vendors of biometric identities and they have a very high degree of confidence in the ability of a biometric to be used either on its own or in conjunction with very simple other sources of authentication. If you talk to other people who use different types of technology, they rejected biometrics either because they didn't think they would work or they didn't think that the cost of the technology would work well within their institution. So we can certainly do a little bit of digging, but I personally don't think that in terms of this committee setting policy, that we necessarily need to know the answer to that question in order to address some basic policy around authentication.

Judy Faulkner – Epic Systems – Founder
Okay, and if the answer—

Deven McGraw – Center for Democracy & Technology – Director
Because I don't know that the answer's out there at a level where we could answer the question.

Judy Faulkner – Epic Systems – Founder
If it isn't out there, but if the policy says that if there is a single strong metric we can use, then that can cover it if that's found later on to be strong.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Paul?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
With my simplistic mind, I try to look for overarching solutions to multiple problems. The problem that Larry raised about the many dongles or not only the provider but the patient authentication, about ten years ago I think there was a law, ESIGN, I think it was called, and it talked about digital signatures. I think NIST was supposed to come up with a standard. I don't know where that is and wouldn't it be nice if

there was a way that everyone in the country could identify themselves and that essentially with one fell swoop put an end to the whole problem. I don't know whether we can look into that, where that is, or even part of the recommendation being wouldn't it be nice if we actually executed the ESIGN.

Deven McGraw – Center for Democracy & Technology – Director
We should look at that. I think the other national initiative that is ongoing and is still not done is the National Strategy for Trusted Identities in Cyberspace. People are looking at the issue of being able to authenticate yourself as an individual for doing activities on the Internet and for interacting with government beyond the healthcare sphere, which is directly relevant to what we're doing. Unfortunately, they're on a slightly different time table than we are. We thought we'd like to have some recommendations ready for consideration for National Health Information Network governance, for example, so waiting until the end of the year is not really a great option for us. But I think it is instructive to thinking about where the policy guardrails that we would want to set down given where we are in this moment of time when things are changing so rapidly and there's other initiatives going on that have direct relevance to what we're doing. We might not want to be so specific in light of some other things that are coming down the pike.

David Blumenthal – Department of HHS – National Coordinator for Health IT
We need to move on to PCAST, but just a couple of points. When ONC does issue a governance NPRM and tries to set up a governance rule, it will be trying to realize the goal set out in the HITECH legislation to create a nationwide interoperable private and secure electronic health information system. In so doing it will have to put the federal government's assurance behind whatever it recommends. So the question that we've burdened the tiger team with and that the Policy Committee will have to deal with is, and that Gayle nicely poses for us, is what's sufficient assurance so that people will trust it and so that we can all sleep at night saying, yes, we've done our best. We've gotten the right balance between utility and risk.

There will not be a controversy free solution, but we will have to pin it to something that we can reference as an authoritative source. We can't just pin it, and, Marc, with all due respect, we can't just kind of say you have to assure us that you've done something because assurance will then be in the eye of the beholder. For some people a password will be sufficient assurance and they will become members of the Nationwide Health Information Network with all the privileges, but they will be an extraordinarily weak link in that chain and Intermountain will be vulnerable to the weakest link. So it's a collective problem and the more freedom that we give people, members of that network, to determine their own solutions and the greater the variety of the solution, the more complicated it is to create that level of assurance. I do think we will have to, in recommendations, bite the bullet on some standard, it could be a NIST equivalent standard, but some standard that is secure enough so that we can tell the American people they can trust it. That's not an easy thing to do, but it is a requirement, I think, for what we want to accomplish.

Two factor may be too much for some systems, and if that's true we may just have to say well, that's great. You don't have to have two factor authentication but then you can't participate. You can opt out of the Nationwide Health Information Network with all the conveniences and burdens associated with that and your patients will know that you're not a member and that you can't provide the assurances that go with being a member. But we're the United States, we don't force anyone to do anything and if you don't want to have your information be as secure as the Nationwide Health Information Network is, you don't have to have it be that secure. And that may be one way we can give people the freedom to get outside of the inconvenience but also provide those who want to know that their information is secure, something the federal government can stand behind. I think that's one perspective to take on this.

Anyway, thank you very much. I hope we were helpful to you. I don't know if we were.

Paul Egerman – Software Entrepreneur
It was very helpful. Just before we ..., there's actually one more question that people wanted to get back to us with their thoughts on, which is we were only looking at remote access and the question was, should we also dive into access within the enterprise? Dr. Blumenthal, your comments about participating in NW-HIN sort of suggest maybe the answer to that is yes, in terms of the weakest link.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Yes, I don't want to tell you what you should decide, but we would actually value your thoughts about it. I think it's part of the chain, so rather than just kind of saying it's off the table, you could say we think it's important, or we don't think it's important, and give us the reasons why.

Paul Egerman – Software Entrepreneur
Okay, it sounds good.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Great, thank you very much. You get to stay, Paul.

Paul Egerman – Software Entrepreneur
Yes. I'll just say good morning. I'm here for the PCAST Workgroup Report. Thank you, Dr. Blumenthal, for that kind and interesting introduction.

David Blumenthal – Department of HHS – National Coordinator for Health IT
You're still courageous.

Paul Egerman – Software Entrepreneur
Thanks. I was asked to talk about what's going on with the PCAST Workgroup. As you know, we had a hearing a few weeks ago, and after the hearing we had the HIMSS meeting, so we actually haven't met since the hearing. But I'm going to do a quick refresh. These are the members of the workgroup. Not listed here are the ONC staff members who are really doing a great job in terms of helping us, and that's Jodi Daniel, Doug Fridsma, and Jamie Skipper. Judy Sparrow's really been fantastic, because we've put a lot of stress on you, so I just wanted to say thank you for all of that help.

This is the workgroup charge. We have an interesting charge and an interesting challenge, because the PCAST Report is a very interesting report. It has something in it for almost everybody, which means that almost everybody can find something in it that they like or they don't like. We are really not making recommendations about the report. We're simply trying to evaluate the implications of the report on ONC's policies and strategies. We've had this workgroup hearing, I should also mention my colleague, Bill Stead, can't make this presentation, and what you see here is the results of at least Bill and I, Dr. Stead's and my evaluation of what we saw from the hearing and also what we've seen from the public responses and public comments we've gotten.

We had four observations. The first observation is that the PCAST Report is by itself not well understood. To me that's not a surprise. You've got this report that's about 100 pages long, it uses language that people are not familiar with or comfortable with, it talks about things like semantics and syntax and data, things that people just aren't used to dealing with, and they're also just not used to a 100 page report describing a goal. That's not how things usually work. Usually you get a five page article and an abstract one paragraph long. So this is a lot of material and the report itself is not well understood.

The other comment we have is that there's an absence of consensus about the report, and the absence of consensus in some sense, and when I talk about absence of consensus, I'm not talking about the workgroup itself, I'm talking about actually our industry and the people who present it. We see that there's a complete range. We have some people who are very excited, very enthusiastic about the image that's described in the PCAST Report. They look at it and they say, yes, this is exactly right. They're very affirmative, very excited by it. We have some people who are very interested in it, but are kind of skeptical. They said, well, I've seen ... presentations before. I've seen reports. I want to see if this really works. Then we also have people who are 180 degrees separate from the people who are positive. There are people who say they understand it, they understand the concept, but it's wrong. They say we don't need to do this. This is not the right way to go.

You see that very clearly in the public comments. There was a question that was asked about standards, I believe the question on standards related to language standards about how you exchange information, and the public comment was very clear. Some people said, yes, you have to have a new standard. You

have to do all this metadata tagging. Yes, that's the way to go. Some people said, no, you don't have to do new standards at all. The current standard, CCD, or some people said CCR, is all you need. We don't need anything new.

So there's a clear absence of consensus, and from the HIMSS conference I'd be curious to know if people had different observations after HIMSS. But my observation after attending HIMSS was it didn't strike me that the PCAST Report was a major topic of discussion. Very few people seemed to be even aware of it. People who you would think would be aware of it, they weren't trying to sell it in a booth; it was not a major issue. But again, probably none of this should be a surprise. You can't expect an entire industry to read a 100 page report and inside of two or three months say, yes, that's it, we're going in that direction. It's going to take something more if this is what we want to do then just issuing a report and expecting something to happen. That's the second comment I had about the hearing and the observations.

The third comment is simply to say privacy and security, that's a recurrent theme and a recurrent subject. That's not a surprise because any time you have a concept that three people nicknamed and they call it information liquidity or data liquidity, so you're talking about information liquidity is like the privacy and security people are going to immediately wake up and say that's a big issue. I do want to make sure I say that the feedback on privacy and security was not just an expression of concern. There were some very positive things said there. Some people were very excited about more granular choices, they thought that that was a positive thing, the PHR and patient access was viewed as positive, and that was not just from the consumer advocates, but it was also a view from providers, so I wanted to say that.

The fourth observation that we had was the timeframe (2013) as a concern. In one sense that may not be directly related to PCAST, but the sense I had from the hearing, and I had this sense also a little bit from HIMSS, was you got a sense of an industry that's stressed out right now. As you made a comment about earlier, has the government had an impact, and the government certainly has had an impact on our industry and there are people who are very much stressed out that are trying to figure out how they're going to do meaningful use stage one. They are very worried about just how much is going to be in stage two and how they're going to get that done. There's this wonderful thing, ICD-10, that's in 2012, which is this cloud over a lot of CIOs, and so these time frame concerns we got from a lot of providers, especially from the CIOs. We also got it from vendors, who had the same concerns. So those are the common themes.

Now, while I say there was absence of consensus in the industry, actually among our workgroup the more we work with the report I think our workgroup members are getting a greater sense of understanding of the report. I don't want to jinx it, but I think in some areas, we actually are getting some consensus within the workgroup about how to approach some things. I'm not sure of that, but the way we're going to approach this issue is we're trying to approach it by saying two things. What are ONC's alternatives? Also, what alternatives does ONC have to how they implement those alternatives? That's a little complicated, but the "what" part is like the technical side. So this is going to be the Standards Committee stuff, but it's like what are the metadata standards all about? What does it mean to be atomic? How do we deal with this issue about atomic versus context? So we're going to create some alternatives around all of that.

The "how" part is a little bit more like policy issues, is to understand how this all fits into the framework of meaningful use and what actions ONC could take, assuming that the talk technology is defined. We had three different possible approaches. This is a little bit complicated to explain the slide, mainly because after I wrote the slide I changed my mind as to what it really meant, but basically as you think about this entire process what we've got with the PCAST Report is we've got this sort of architecture, it's more like a direction, it's a concept. It's a concept of how data elements and healthcare information can be accessible on a national basis.

So the question is, well, assuming that we work out the details of how that all works, what is ONC supposed to do to actually implement it? We have three different ideas of approaches, and this is a work in progress. We have a three hour meeting tomorrow where we're going to go through this material. One

approach in here says the UEL approach, and one way to think about this is this would be like a technology approach and with this approach what you would do, or ONC might do, is do some things in stage two, do some pilot projects, and between stage two and stage three to test out some things. Then let's say a pilot project we do, say, at the VA works out great and then what ONC would do is say, well, here's the architecture. So at stage three ONC would say here's the complete architecture for how this is all going to work. We tested it all out. ONC would define the architecture and the meaningful use criteria would look something like use it. That's what meaningful use would be.

The second approach would be like a pilot approach. We do a pilot with, let's say, the VA and with other organizations and you pick and choose the pieces that work right and you implement those. Your meaningful use criteria from the standpoint of saying something like well, these are the things we did, maybe we figure out a way to do medications right, and so now you write some meaningful use criteria that really would require you to use whatever it was that you felt that you got from the pilot projects. So as you think about the things I just said, from an engineering standpoint the first concept is like a top-down architectural approach, where the second one is like a bottom-up. If you think about it from how people implement medical record systems, the first one architecturally is almost like implementing a complete medical records system. The second one is more like a best of breed, where you put things together sequentially. Those would be two different approaches.

The third approach is the market approach, which is a little confusing to explain. But with the market approach basically it says well, people look at the Internet, and it was very interesting, people look at the Internet and they look at this concept of something called the ... Ulta Log system and it's easy to use the Internet as an analogy for whatever it is you want to argue for. To do that, if you look at the Internet, one way to look at the Internet is you've got this communications protocol, TCP/IP, that's a baseline protocol for how you communicate, and you've got government deregulation that basically created inexpensive, ubiquitous connectivity. But really what happened there was that different people simply layered on top of that all kinds of interesting standards and structures to solve specific problems. It wasn't like there was a design for an architecture. It was really things just happened. As they happened there's not necessarily a great argument about what's used and not used. Some things are done synchronously, some things are done asynchronously, there's places where there's two different ways to do things, but people just did what would work on that baseline platform.

The idea there, the third approach that we could think about would be to say well, what ONC does is understands all these issues but really looks at what are the fundamental building blocks that it really needs to do. So instead of defining an architecture, it defines what are the connectivity pieces and the exchange language pieces that it needs to do and it defines standards around those, but does not try to define the entire architecture.

To think about this, even in the context of David Lansky's presentation earlier today, in the third approach what you do is your meaningful use criteria would simply be whatever you needed to say about meaningful use, or whatever the goal was that you're trying to do to improve patient outcomes. In theory with this third approach then you would either have to have certification criteria or something to build something or people would just be able to do it themselves. Now to talk through the other approaches, the first two approaches, in theory with the discussion that we had this morning about quality measures if you actually implemented an entire architecture everything would be in place already to do whatever you want to do with quality, and whether or not that's correct I don't know.

But those are the three approaches. I don't know if that made any sense. We're aiming towards an April 13th report and there's something I'm going to ask for your help on, but first let me stop, I've talked for a while, and see if people have any questions or comments or anything that I said made any sense.

Deven McGraw – Center for Democracy & Technology – Director
I'm trying to understand, personally I find the pilot approach to be very appealing and I'm struggling with trying to understand the difference between number one and number two, which both seem to call for pilots.

Paul Egerman – Software Entrepreneur
They both call for pilots. Number one, though, is a concept of, it's a complete architecture. In other words, you do your pilots and you implement a complete architecture for exchange. With number two, you might do a complete but you might do something less. In other words, you might say, well, we got this worked out for medications but we didn't get it worked out for lab tests. We're not sure about that piece, so we're going to do the medications part. You do something less or you may mix and match. It may not architecturally fit really neatly, but you have one solution for labs and one for medications. They're just a little bit different.

Deven McGraw – Center for Democracy & Technology – Director
But both of them involve really pilot testing approaches before we would ever launch them live, which seems to make a lot of sense.

Paul Egerman – Software Entrepreneur
Yes.

Deven McGraw – Center for Democracy & Technology – Director
Okay.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Paul, then Gayle?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Thanks, Paul, for summarizing a complex topic and hearing. Reading between the lines, and if there aren't pilots, and we heard about that during the hearing, and it isn't something that's been fleshed out and tested, going back to what Gayle said about even testing quality measures, one would think that that should be a precursor to introducing it to a nationwide program such as meaningful use. That seems to go to the same conclusion that Deven had, which is sort of like two heading towards some future year, but 2013 is really almost upon us. Does that make sense? It seems to move us away from one. If there isn't really an instantiation of this already, if there isn't a pilot done on a broad scale, wouldn't it be too early to advance even the elements, let alone the architecture in meaningful use stage two?

Paul Egerman – Software Entrepreneur
I don't know the answer to that. Again, the workgroup is meeting tomorrow. There is some enthusiasm for doing some things in stage two to advance the process, and so I think it is possible and likely, we'll come up with some candidates for some advancement within stage two, of the processes. We also have to keep in mind there was a very clear thing in the PCAST Report which said, "act aggressively," and used the word "boldly" several times. Again, the way this works, we will come up with candidates and we'll hand it to you, so everybody here will have to decide if that makes sense in the context of everything else that's going on.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Gayle?

Gayle Harrell – Florida – House of Representatives
Thank you very much. So many of us were at HIMSS and found it absolutely fascinating, perhaps, the lack of discussion on the PCAST Report.

Paul Egerman – Software Entrepreneur
Although I attended one really excellent presentation on it.

Gayle Harrell – Florida – House of Representatives
To me, I think what I saw and the reaction I got from a lot of people in discussing the PCAST Report, because as you all remember from my comments at the last meeting, I am somewhat distressed over it in that we are now on a pathway. I know what we're doing in the state of Florida, having just led a $19 million contract on developing our statewide HIE, where PCAST would have us go we're going to have a

different architecture and it's going to go somewhat in a different direction. Currently we're spending in the right direction, and I want to make sure we do this wisely. My sense of things was people viewed it as more aspirational than perhaps a road map, and perhaps that's where we need to go eventually, but we have lots of steps and stages to go to get there. Certainly, the universal exchange language seems to be a stumbling block in how you get there rapidly with that, but I think the sense of things was more aspirational as opposed to directional and road map in place to do it. But I think from my perspective on what we do, we need to in stage two of meaningful use, we need to really look carefully and not preclude going in specific directions through stage two. So perhaps stage two is more of a slower ramp up to stage three if we're going to change direction. I don't know that. I think this group as policy makers or recommending policy to the ONC really needs to have this very rigorous debate on that before we move forward.

Paul Egerman – Software Entrepreneur
Your comment about aspirational is good, because one observation I would simply make is ONC's done a really good job of balancing, at least so far have done a good job balancing our aspirational goals for pragmatic realities. So that's just the way it is on a lot of things –

David Blumenthal – Department of HHS – National Coordinator for Health IT
Larry?

Paul Egerman – Software Entrepreneur
....

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
Maybe I'm channeling Wes Rishel here, but in the three pieces I see, top-down, bottom-up, and middle-out, and he would certainly be advocating that you want to architect to the middle. You want those key capabilities that don't constrain the specific implementation and don't define all the use cases, but give you core capabilities, which is what you seem to be advocating the market approach would give us. So that might be a way to frame the distinguishing aspects of the three.

Paul Egerman – Software Entrepreneur
That's helpful, though, I did not intend to describe it in such a way that I was advocating for one.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
That's okay. I understand.

Paul Egerman – Software Entrepreneur
I was trying to describe that these are the choices. I don't know for sure whether or not the workgroup will see it the same way. We view our job as not necessarily to advocate for it, but simply to lay it out.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
I understand, but in terms of a framework to distinguish among the three, that they could be top-down, bottom-up and middle-out.

Paul Egerman – Software Entrepreneur
That's a better way. I wish I had done it that way instead of the way I did it for the slides. I should have called you.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
Great. Next time.

Paul Egerman – Software Entrepreneur
Absolutely.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

Picking up on the HIMSS theme, a friend of mine walked the show floor and she came back and said two themes stood out to her. One was workflow, which we'd come back to a lot, that it had to actually be efficient and effective in delivering the technology to clinicians. Then the second was interoperability. I wonder if some of the directional focus from PCAST in fact was being translated by people into interoperability, that it had a particular spin on how to achieve interoperability and what it is we're interoperating with. But the ... topic of the need to share information really is a top of mind topic and a lot of people are working on it.

Paul Egerman – Software Entrepreneur
Good observations.

David Blumenthal – Department of HHS – National Coordinator for Health IT
A couple of questions. First of all, as I understood PCAST, and I may not have understood it very well, they really wanted some combination of one and three. Actually, pieces of all three of those solutions were included, so they want a certain foundational set of standards that are top-down. They believe that will enable a surge of innovation from the bottom-up, Internet-like. Then they're not averse to testing some of those standards in the form of pilots while we roll them out. So I wonder whether the three approaches you have are reconcilable in some kind of grand synthesis, or whether that's naïve. That's point number one, that's a question. You don't have to answer it here, but I would be interested to know from your workgroup whether that's your opinion.

The second thing I would be interested in your workgroup's opinion on is that the PCAST Report conveys an enormous sense of urgency, almost beyond urgency, as though there is a ticking clock. If we don't act by stage two of meaningful use something valuable and irretrievable will be lost, that is, a certain architecture will be frozen into place that we will never be able to free ourselves from, and that the interoperability they envision will never be accomplished. I would be interested in whether the working group sees any such time frame operating, whether they think there isn't that kind of urgency, whether we are in fact on a course that could be disastrous if we don't change it. Because I would say if there's one thing that is compelling to senior officials in the administration is that sense of urgency, that there are opportunities being lost in a matter of months and having some external validation of that or contradiction of that viewpoint would be extremely helpful.

Paul Egerman – Software Entrepreneur
Sure. So to respond to the two questions, the first one is you're asking if there's some synthesis. I wasn't sure if you're asking with each other among these three things, or between these three things and the PCAST Report.

David Blumenthal – Department of HHS – National Coordinator for Health IT
That's a good question. Yes, I guess it's among those three approaches, because I think the PCAST Report envisions all three.

Paul Egerman – Software Entrepreneur
Yes, because I think the three approaches are consistent with the report and I actually think that once we start walking ourselves through them we're going to find that if there's not what you call synthesis there's a lot of overlap, that these are not as different as we might think they are.

On your question of urgency, that is an issue that we will be addressing tomorrow, which is we're going to be saying, well, what is feasible to do in stage two and how do we understand that call to urgency in terms of what is the impact. One of the interrelated questions is, is what PCAST is saying really all that different from what ONC is currently doing, because there's also an argument that says, well, maybe there are some technical things that are different. But there's an argument that says this is actually in some ways surprisingly close to many of the things that are already happening. So that also could be part of the response to that question.

David Blumenthal – Department of HHS – National Coordinator for Health IT

Well, it is noon and it's time for lunch. I want to thank Paul in all his guises, with all his identities, as well as the other folks who have testified or presented their work today. Paul Tang will take over after lunch. Yes, Paul?

Paul Egerman – Software Entrepreneur
One other thing I was going to say, we will be back, and when I say "we" I'll have Bill Stead with me, on April 13th, which I think is the day for our April meeting, to present. The one thing I'm going to ask people to do in advance is we're going to send out with each of our meetings the documents and the PowerPoint slides and everything, and we ask people to read through it all in advance and to ask us questions. We have a lot to do in April because we're going to have to go through all the meaningful use stuff also, so that's one thing I will be asking for the month of March is to do your best to go through. Hopefully our stuff won't be as long as 100 pages, but you never know, so that was my one request.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Thank you, Paul.

Gayle Harrell – Florida – House of Representatives
I have one more comment. I would just like to comment that I understand this might be your last meeting with us, Dr. Blumenthal.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Thank you for asking. If we meet on April 13th—we do—then I may be here for that meeting.

Gayle Harrell – Florida – House of Representatives
I would hope that you would be, but if you're not I just want to extend my best wishes to you and congratulations for continuing back at Harvard, and let you know how much I personally appreciate your leadership.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Thank you. I may haunt you all on the phone. I may be a member of the public listening in on your meetings.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Our final panel for today, taking the spot formerly held by Privacy and Security after lunch, is the Information Exchange Workgroup, who has a series of things that they would like to discuss for us on the way to making recommendations. As Dr. Blumenthal mentioned this morning, because we just received this material this morning, we'll postpone an actual decision on it, unless the group feels comfortable with it, until the next meeting. So take it away, David Lansky, Micky Tripathi, and Walter Suarez.

David Lansky – Pacific Business Group on Health – President & CEO
Thank you very much. Micky, do you want to tee up the presentation we're going to have from Walter and Jonah?

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO
Sure, I'd be happy to, David. Unless, are you there in person?

David Lansky – Pacific Business Group on Health – President & CEO
Yes, I am. I can do that if you'd like.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO
Okay, that would be great, if you don't mind. I'm here for support.

David Lansky – Pacific Business Group on Health – President & CEO
All right. Micky has been certainly our fearless leader in getting us down this path, so as you all recall, the Information Exchange Workgroup has taken on really two very closely related initiatives to sort out

both the entity level, the enterprise level provider directory requirements, and then very closely related to that the individual level provider directory requirements.

The next slide I think gives us a list of people who have been very active working on the workgroup as a whole, and then very strongly supporting and really driving our work around these topics has been this Provider Directory Taskforce, chaired by Jonah Frohlich and Walter Suarez. They have really done extraordinary work in a very complex area to try to sketch out the set of functions and requirements that are needed and the policy implications of those proposals to allow the states who are feeling a great deal of pressure to build out their HIE functions to have a reference point of how to think about the provider directory capabilities that are needed to support HIE and in particular in the state implementation program.

So we had come to you previously with proposals regarding the enterprise level, the entity level, and we are now coming back to you today with a set of recommendations that again we'll present for discussion today and hopefully feedback and understanding any concerns that might exist on the individual level directory. We're fortunate to have Walter with us today to walk us through the substance of that. Again, it's been a really hard working and productive group, and thanks to Walter and Jonah for leading it.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Thank you, David, and Micky. My name is Walter Suarez. I'm with Kaiser Permanente. I'm, as David mentioned, one of the co-chairs of the Provider Directory Taskforce and a member of the Information Exchange Workgroup. Jonah probably is on the phone as well, so he will be available and able to fill in some of the points as well if we need to.

What we wanted to bring to you today is a series of recommendations around the second type of provider directory that we discussed over the last three or four months. As David mentioned, we came back several weeks ago with recommendations on the entity level provider directory. We developed a framework to talk about provider directories and define those recommendations, and I think it's in this next slide. We developed that for the entity level provider directory and we are using that same framework to develop the recommendations for the individual level provider directory.

So we talk about the participants of these directories, the users and the uses even to the directory. We talk about the functions and make recommendations around the functionality of those directories, the content, the information that will be captured in the directories, some of the operating requirements and business models for moving forward with the implementation of provider directories. Again in this case individual level provider directories, and then some policy recommendations that address critical policy issues; all of this is what we will be going through this afternoon. I will be talking about each of these points and seeking input from the members of the committee.

Let me move forward and start with, I'm going to go through this next slide, definition of the individual level provider directory versus the entity level provider directory. I think it's important to put this into the context of these provider directories are intended to be resources that are electronically searchable and that will include information about the providers, so whether it's individuals or entities they will have that information. The individual level provider directory will have information about the individuals, the entity level provider directory about the entities, the names, addresses of the identification information, and that is going to be used to support. This is one of the core elements of functionality of this directory, is to support the secure and reliable exchange of information. So its primary purpose in this case is to support those exchanges of information. If one entity wants to send information to another entity and doesn't know what the right address, if you will, or location, and doesn't know what are the information exchange capabilities of that entity and needs to know the security characteristics, if you will, of that entity, they can seek those and discover those, as we call it in the directory effort, discover those and then use them to create this exchange.

Those were the two types of directories that we worked on. The value proposition for the individual level provider directory comes down to this point that I listed in this slide. Users really are going to be able to identify and verify the recipient of the information and do electronic links via the ILPD instead of really

having to do an in person contact or manual contact of those recipients. So this will simplify certainly the workflow and create the automation potential benefit to the system in that way.

The user system no longer will be responsible really for maintaining its own ILPD, so this will share the cost, the responsibility of maintaining the ILPD information will be on the individual that is listed, or individuals that are listed in that directory. This will spread the cost basically of maintaining those and certainly improve the quality of the information. The user system can determine what information exchange capabilities are available at each recipient, so this will provide for an enriched content transfer, enable more automation, and reduce errors. The last point about the value of these ILPDs is that the user can potentially query the ILPD for additional information. In the future, there could be other uses of these individual level provider directories that support other types of functionality, like administrative transactions and other things. Those were some of the value propositions of individual level provider directories.

In the next slide, we describe basically the two types of recommendations we're presenting. The recommendations fall into one of these two categories, recommended practices, so a series of practices that we're recommending for ILPD operating entities, entities that operate individual level provider directories, that they should consider when establishing and operating this directory; and then some areas that require some basic interoperability to be enable. So, for example, say we'll have different use cases for ILPDs that will require varying content and functionality, but in order to make those ILPDs interoperable there needs to be at least a minimal level of standardization across them. That's one of the set of recommendations we make.

A few assumptions in framing this provider directory set of recommendations for the individual level of provider directory. We believe that really the ILPDs already exist; many, many organizations already have ILPDs, many HIEs are developing provider directories at this level, so we believe that at the end it's really a sub-national level of effort that is going to be what will work. Trying to centralize and create a central repository of all this information in one single place for individual level provider directories would be too complex, and ultimately the information resides at the local level with these provider directories and that's where it gets maintained. When these two happen really again is to establish this minimum set of standards to allow them to interoperate. The expectation is that there would not be rigid conformance to a very comprehensive set of national standards, but a minimum conformance to a basic set of standards that will be needed. And then entities can add and expand at the local level for additional functionality.

As I pointed out, states are currently implementing already ILPDs and there's a clear need to produce a recommendation in a short term fashion rapidly. So the focus of what we are recommending will be on the kind of best practices and examples of how ILPDs can be established and maintained and operated, and some of the policy levers that states and others can use to create incentives for individual providers to participate in this ILPD. Some more assumptions, the ILPD listing would provide enough information to enable the resolution of the appropriate destination of a message. So an individual that is searching for a practitioner, another individual on the ILPD will be able to find perhaps one or more that potentially match, but that's one of the assumptions is that there will be enough knowledge in the requester of that information to sort between the various potential matches of the individual. Then once they have identified the individual, the record would include potentially multiple locations in which this individual practices.

So again, another assumption is that the requester will have enough knowledge to sort through the various locations that might be listed in this record of that individual and point to the correct location. The ILPD is expected to include location listings for each of these individual providers and would have a relationship, a many-to-many relationship with the entity level provider directory. So, once I have identified an individual and sorted through the various locations, identified the location, I will be able to link that with the information about that location in the entity level provider directory and then be able to pull out of the entity level provider directory the information that I need in order to execute the exchange.

As a reminder, on the recommendations on entity level provider directory a couple of the functional elements that we recommended was that the entity level provider directory will provide information about the exchange information capability. For example, this entity is capable of receiving HL7 2.0 messages, or CDA, or this or that, as well as the discoverability of the security certificates. Not the certificates themselves, but the ability to discover information about the security certificates that the entity has. Those were elements in the entity level provider directory that can be accessed by this connection between the ILPD and the ELPD. The primary value proposition really is the exchange of clinical documents where providers have only basic information about another provider that the patient is seeking care from and needs to locate their practice. That's what the individual level provider directory will support.

Okay, so let me get into the recommendations. We're going to start, first, if you'll recall, the framework we have, the participants, the users, and the uses. With respect to the participants, what we're recommending certainly is to include in the listing of individuals that are able to be noted in this provider directory any and all individuals that are healthcare providers who are licensed or otherwise authorized by a state to provide healthcare services. And that are individuals that are involved in Health Information Exchange transactions, whether they're the receivers or the seekers of information, and that need to be identified at the individual level for purposes of receiving or requesting health information. So those were some of the conditions. This means that physicians and any other practitioner that delivers healthcare services and that needs to be identified involving exchanges and identified specifically for those exchanges. So that's a recommendation about the participants, a very wide cast of individuals.

With respect to users, what we recommend is that certainly there will be access restrictions to the information that is contained in the provider directory, so users will have to have authorized access to this individual level provider directory content and they should include clinicians, support staff, individuals that have valid reasons to access the information from the provider directory. Well defined roles and rules-based access policies will need to be salvaged by the operator of the provider directory to enforce those access controls and the expectation is, and the risk certainly is that there would be some sensitive information about individual providers and that that information needs to be controlled and restricted. We heard earlier in the discussions of the committee the concerns about medical identity theft and fraud and abuse, and these are the kinds of situations that could be gained by having full access to this provider directory at the individual level. So that's the reason we recommended a control access to the individual level provider directory.

Then with respect to the users, just like we did with entity level we developed a series of use cases and use case scenarios in which we describe the process by which an individual who has been searching for. Another individual will use the individual level provider directory to identify that individual, identify the locations, and then identify through the connection to the ELPD the organization information to execute the exchange. We created seven different scenarios; both push and pull scenarios, for clinic to clinic exchanges, hospital to clinic exchanges, public health alerts, and investigation exchanges. So the need for public health to push out messages, or to pull the information about an individual provider to obtain specific information about a particular case, for example, then a lab to clinic exchange, a push scenario in the lab to clinic exchange. So those were scenarios, we have them documented in the attachment to this presentation and so I'm not going to go through in great detail on each of those scenarios. They're very similar to the scenarios we describe when we talk about the entity level provider directory. Certainly if we need to at the end we can jump in to any particular example.

But what we wanted to present here is the common threads across all the scenarios, and basically these are the five or six points across the board. The submitter needs to send a message to an individual provider. The submitter has some information on the individual, but does not know the location of that individual. The ILPD then is used to identify the individual and the possible locations. With additional information, as we mentioned in the assumptions, the submitter will identify and select the appropriate location. Then the ILPD links to the ELPD to obtain the security credential information and the information exchange capability of the entity that will be receiving that message. Then the submitter will be able to send that data and the message to the intended recipient in the appropriate location. So that's basically the common thread across the different scenarios. There are certainly a number of privacy and

security considerations with all the scenarios. Certainly the intent and the expectation is that all the users of this and the use cases that reflect that are going to be contingent to and required to follow all the federal and state privacy laws and rules related to the protection of information.

As you can think of in these provider directories, there's no individual patient level information contained in this directory. There are individual, in this particular one, individual level provider information that is included, and that creates a certain level, certainly, of sensitivity and concern. We also noted that a pull use case adds another layer of complexity that requires a strong focus on following relevant privacy laws, primarily. Because the pull case assumes that I'm going to go and seek information from some entity and from some provider, an individual provider, so I am going to have to be authenticated and authorized to access that information.

We just had an extensive discussion earlier, the committee had an extensive discussion about the authentication issues, so we're certainly intending and expecting that these provider directories will be complementary to the requirements that will need to be put in place with respect to authentication and authorization of individuals seeking information, those were the participants, users, and uses. The content of the directory, basically the data that will be expected to be included about each of the individual providers listed will be primarily data that is needed, minimal based data that is needed to identify the individual and to provide the practice location.

So the recommendation is in number two, that the information about individuals will primarily focus on demographics, the last name, first name, provider type and specialty, name and address, practice locations, and some other demographic and contact information. Then the potential identifiers, certainly a number of identifiers, including the NPI, the DEA number, the state license number and others, again, consistent and depending on the ability to include those in these types of directories based on regulations. But this type of information is the kind of information that becomes sensitive and at risk of being used for things like medical theft, identity theft and fraud. These were the main data content elements that we were recommending to include in the directory. In order to serve its purpose, the information will need to be authoritative, representing basically all providers and types covered, and accurate. The accuracy and the validity, the reliability of the information is very critical here. That's why the intent is to really push it down to the end user. There is a potential opportunity to use existing sources of content to populate and to validate some of this information that helps ensure the data integrity, so these were basically the recommendations about the content.

Let me go to the next slide. Functional capabilities of this directory, basically we see four primary functional capabilities. Number one, supporting direct exchange functions, both send and receive as well as query and retrieve. Provide basic discoverability of an individual provider and their practice. Provide basic discoverability and linkage to an individual provider's ELPD listing and entity level listing. And then support a strong audit trail capability consistent with the fact that this provider directory will have controlled access, and so the need to maintain control about who is accessing the directory and what is being done, as well as control around the edits and updates of the information in the directory.

Some operational requirements, and here we listed about 11 or so operational requirements that we believe are very important for ILPD operators to follow. The way we frame it is basically ILPD operators should follow all these requirements. Number one, establish defined policies and procedures and provide a structured and secure mechanism for individual providers to enroll and verify information used to populate the ILPD. So a critical step is to establish those policies and procedures about the individuals that are going to be listed and the information about them.

Establish policies and procedures to verify as appropriate information provided by an individual enrolling in the ILPD. So not only will the individual be able to verify the information that is pre-populated, but there will be an expectation that the operator will have to have procedures to verify the provider derived information, the information provided by the individual requesting to be listed. Data elements included should at least meet the minimum data set recommended by ONC through this set of recommendations being brought to the Policy Committee. These data elements should follow national standard definitions for content. So here is really a very important element because I think there is going to be a need clearly

to define the structure and content of these provider directories. This applies not to the ILPD, but also to the entity level provider directory, so the content, the data elements in it, the definition of those data elements are going to be critical to make those directories interoperable.

Number four, establish policies and procedures that define who can access and use the ILPD and which data they can access and see. This is, again, consistent with the concept of restricted access. Number five, ensure that the ILPD is able to interoperate with other ILPDs, developed and operated in a manner consistent with these recommendations so that ultimately the goal is to make sure that they do interoperate. Number six, and again we have about eleven of these, so number six, provide a mechanism for individuals listed in the ILPD, or their delegated authority, for example, a staff person that is going to be provided that too, be able to log in, to enter into the system and perform some maintenance, correct, update listed information. An update and resolution process and change control policy should also be put in place by these operators, and again here's another reason why the audit control and audit trail functionality is critical in these ILPDs.

Number seven is establish policies that require individuals listed in the ILPD to update periodically their information, at least three times per year or as changes happen in terms of their practice location and affiliations. Number eight, develop and put into place audit trail policies and procedures to track ..., as well as investigate inappropriate uses and breaches of the system. Number nine, ensure that there is accountability and a shared responsibility managing provider listings, so delegating pretty much the responsibility of maintenance to the individual that is being listed in these directories. Number ten, develop procedures and a set of policies to establish appropriate linkages between the ILPD and the ELPD records, update a provider's ILPD listing with their affiliated ELPD listings, and then allow the interactive access to the ELPD information once it's been pursued through the ILPD connection.

Lastly, implement security policies and procedures that ensure that, number one, the data contained in the ILPD is appropriately protected and only accessed by authorized individuals, authorized individuals that have access to the data for purposes of updating and changing the information, and access to information contained in the ILPD by external users is appropriately managed.

These were our operating requirements for ILPD operators. Now, a few considerations and recommendations regarding the business model and some of the policy areas, clearly, we see that without sharing this responsibility for maintaining the reliability and validity of the data in the directory, the cost of keeping the content in some old way will be unsupportable. So operators should consider models where providers or the delegated entities are really ultimately accountable for that accuracy in the listing.

ILPDs have limited intrinsic value in themselves, so the opportunity is for the ILPD operators to add value to the ILPD itself by expanding in other service areas beyond the primary purpose of the ILPD, which we describe as being a tool for secure exchange, secure routing of information. But there are other values that certainly could exist in the market for these ILPDs and certainly there's the opportunity to add these additional services and value to the existence of these ILPDs. Then number three, services outside of what may be required to fulfill meaningful use requirements that require an authoritative directory, credential, credentialing research, should be considered as services that can be provided by the ILPD itself. So these are examples of the kind of added value that the ILPD could have.

I think the last slide that I have is this slide on policy considerations. One of the recommendations that we wanted to bring forth is that the Health IT Standards Committee should consider the directive to identify and recommend to ONC the technical interoperable standards, including both message and content standards of the ILPD. This is where the definition of the structure and content of the ILPDs will happen and needs to be defined, established. This will be done, we expect, by the HIT Standards Committee consistent with all the other Policy Committee recommendations, the HIT Policy Committee recommendations, these other recommendations that we have brought forth to the committee here. All of this is of course going to be in line with the work that the ONC is doing through the S&I framework.

Secondly, CMS should consider making available the NLR and the PECOS content. These are the databases that CMS maintains on individual providers as well as other providers, but these are the

enrollment systems that CMS maintains for individuals. So make that content available to ILPD services that have been funded through the state HIE cooperative agreement to help them populate the data, validate the data. Third, states using HIE cooperative agreement funds to establish state level ILPDs should make the provider directory resources and services available to participants in private and public sponsored networks. Basically, state entities that are developing through the cooperative agreement these ILPDs should make those resources available to the community beyond the members perhaps of that or participants of the HIE itself, but also to other participants in private and public sponsored networks.

Number four, CMS should consider how they could require Medicaid agencies to incorporate ILPD use as they approve Medicaid HIT plans and fund state EHR incentive programs. So this will be a mechanism to foster the establishment and the use of these ILPDs through the Medicaid HIT incentive role. Then the ILPD that chooses to use ELPD services will be expected to meet a set of participation requirements. Basically, the intent is that all the ILPDs that are out there that will be linking to the ELPD will need to meet the standards and the recommendations that are being established in this proposed recommendation from our workgroup. By doing that the ILPD will then have a consistent way of collecting, maintaining the information about the individuals in the ILPD using standard data content in it and then be able to link and interoperate, not with just other ILPDs, but also with the ELPD itself.

A couple of additional policy opportunities once the standards are adopted for ILPDs. Certainly state HIE cooperative agreement grantees supporting the development of ILPDs would be potentially required to follow the recommended standards coming out of these recommendations, and the federal EHR certification process could also incorporate certification criteria for EHRs to support the exchange and access and connection, if you will, link to these ILPDs.

I think that was my last slide. The next set of slides, when we developed the ELPD we developed a series of recommended common terminology, the descriptions, so we have the definition of provider directory entities, individual, sender, receiver, routing, all these terms that we use in the discussion of provider directories, so we have a base common terminology to reference here. Then again in Appendix 2 we included all the various use cases. This is basically the description of the first use case, the clinic to clinic exchange in the push scenario. So you can see through the various use cases how we describe this exchange need, the ILPD functionality that would support that exchange, and then the achievement of the exchange through the application of the ILPD functionality.

Let me stop there. I don't know if David or Micky or Jonah has any additional comments. No. Okay, back to you, Paul.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Thanks for a very detailed report. I'm trying to anticipate what Dr. Blumenthal might say, and I think part of the guidance might be like the NHIN Workgroup initially. There are almost 50 recommendations here, and as we prepare for the next meeting for approval, if there's a way to consolidate it and maybe keep it at a higher policy level, that might help people digest it. Some of the important things you described are who's in this, what information is in there about them, how people go access it, and what are the permissions needed. I think a lot of people, and I'm going to second-guess Gayle here, would want to make sure, some of the information you described is very sensitive, and David alluded to medical identity theft, how is that protected? I'm not sure you described it. You said we need to pay special attention to it, I think. But some of those things might be of interest to this committee as it goes forward with approving your recommendations in the future.

Other comments? Deven?

Deven McGraw – Center for Democracy & Technology – Director
I think it is a really comprehensive set of recommendations. It's really clear that all of the different operational and business case issues were thought through. I think the one piece that I'm missing here are identification of what specific policy levers you would recommend using. So for example that you need all the participants who are individuals who can be listed in an ILPD should include all healthcare

providers and all who are exchanging, so are you suggesting, for example, a meaningful use criteria that requires meaningful users to be listed in their state's ILPD? There is a mention of the state grant. I think we'd need to investigate whether that's still a monetary flow that's ongoing. I don't know whether there are still opportunities to influence additional criteria that can be put on those, I don't know, I'm just speculating, but in terms of saying here are the levers that we think work for these, and I agree with Paul, almost grouped together, the ones for individuals, the ones for the ILPD organizations, etc.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Yes, that's a great point. We explored a number of policy and technical levers, I guess, to encourage individuals to join, but I think there are many other ways to look at this—

Deven McGraw – Center for Democracy & Technology – Director
Yes, ... look at the wish list would be in danger of not being acted on if it wasn't directed in a certain way.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Exactly, great point.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Gayle?

Gayle Harrell – Florida – House of Representatives
Thank you very much, and you anticipate my comment certainly on the sensitive information, dealing with especially DEA numbers and medical licensure numbers. Those are very valuable numbers. In case you've missed the testimony in the Congress today on fraud, this is a wonderful source of information for people who want to consider going into the fraud business, so I think we need to be very mindful of that. We have a lot of that going on in Medicaid in Florida, and there are hearings today on the Hill concerning that. So I think we have to be extremely careful how this is done and make sure that we put the security and privacy issue, the security of that information very much in the forefront on how that is dealt with.

Also, have you really had—and I've been on several of these conversations, but given my schedule have missed several of them also. We have the state grants that are out there right now and if the state HIE is going to run this, that is I assume your vision of who is going to run the directory, what is the ongoing source of funding? These grants are one-time grants, they're out there, they're to build an infrastructure, but there's ongoing cost to this. I know in the state of Florida we tried to do this kind of thing eight or ten years ago and it cost us $10 million to try and set this thing up. We never got the buy-in of the physicians to do it, they didn't participate particularly, there was a minimal fee that they were going to be charged to get into that, thinking that the insurance companies could benefit from it and pay fees for that, and it never worked. So I'm concerned about ongoing costs of operating this thing. They're not going to be minimal.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Yes, good point. The expectation is truly that if this is a service, I mean, today there are many provider directories out there, every entity that has a list of providers in its roster has a provider directory, whether they call it that or not that's different. HIEs and state HIEs, this is one of the functional capabilities of the HIE itself. So funding the HIE as an operational entity, well, the expectation is that it would include this type of service. It's not exclusively funding this service, in my mind, but it's really funding the whole HIE operationally, all the other services that they provide, whether it's repository services for data, whether it's authentication or cross-validation, or whatever, pure routing. So all those combined result in the package of services that are provided by an HIE, provider directory would be one of them, and so, yes, it will be a matter of how the HIE itself is expected to survive, if you will, or to be a financially stable operation across the board, not just because of the provider directory. That's just one of the services.

So it is a question and a concern to consider, absolutely. But at the same time it's one of the other opportunities that they have. It's a unique service that is needed, that is required in order to achieve full interoperability across the various entities participating in the HIE. So it's a value that they can offer as a service to the community, to the state, to the participant in that HIE, and so again it's all part of how would an HIE finance itself and all its services that they deliver.

David Lansky – Pacific Business Group on Health – President & CEO
Can I respond additionally to Gayle's question, which is exactly the right question? The business considerations slide we looked at earlier, the second point emphasizes that the operator's going to have to figure out what's valued in the market that they're serving. I think the question that Walter said is if an HIE, statewide or otherwise, needs to have this functionality within its overall scope, it's going to have to develop a business plan that's going to support the continuation of that functionality. Hopefully we're creating other incentives which will support meaningful health information exchange, which is in turn enabled by this, and then within that people will have to come up with a business model.

I think what we're proposing here is less prescriptive than supportive, in the sense that we know a lot of HIEs in states are building some kind of provider directory function now and the trains are pulling out of the station as we sit here. Our sense is some urgency about our ability, and ONC's ability, to provide guidance to those trains so their tracks end up pointing in the right direction, and doing that with as much supportive information toward uniformity and interoperability as possible without being overly prescriptive where you're exercising an authority we don't have. That's the balance I think these recommendations are trying to strike.

Claudia Williams – ONC – Acting Director, Office State & Community Programs
Just speaking from the CHIE perspective, grant program perspective for a minute, I actually think there's a clamoring from states for some guidance and structure. In fact, what they would like goes well beyond what I think we're going to be prepared to say at a national level. They would like common data elements. They would like a description of what an API might look like that wouldn't allow for interoperability across directories. Some of those things I think we can take up in the S&I framework context and are appropriate to take up there. In the workgroup, we're intentionally trying to lay these out as useful directions. So the wording of best practices and as we see these things develop and here's some things that should be kept in mind, was very deliberate and understanding that people are at a very formative stage we need to know more about what's working and what's not. But there are going to be some key very minimalist things that we'll probably want to take forward through standards work to get a much more fine grained set of recommendations about how some of these things should work.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Thank you. Paul Egerman?

Paul Egerman – Software Entrepreneur
First, great job. This is a lot of work, I know, and it's a fascinating issue because the more you get into it the harder it gets. It's an interesting thing. I want to echo the comments that were made about the recommendations, and picking up on Claudia's comment, it does strike me that one of the great values you've done here is give guidance to these HIE organizations. So the sense I've had from some of my interactions with some of these people is they're saying basically tell me what to do. This is good that you are doing that in a lot of ways, I'm just not sure that that necessarily has to be policy stuff that this group has to pass on, or is this going to be a set of recommendations that ONC uses. So I think this is great guidance. My question is, I'm trying to understand this interoperability standards process. Are you focusing on interoperability from one ILPD to another? Or are you focusing on interoperability from an ILPD to an EHR?

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
I think there are probably three different levels of interoperability: EHR to ILPD, between ILPDs, and between the ILPD and the ELPD. I hope I didn't confuse anyone. Between EHR and the ILPD, there is a messaging exchange, basically a request for information about a particular individual. Between the ILPDs, there might be some, I haven't thought about that particular one, but between the ILPD and the ELPD there's another interoperability point.

Paul Egerman – Software Entrepreneur
I guess you could call it interoperability. That's more like a pointer. The ELPD points to the EHR, right? It says Dr. Tang belongs to Palo Alto Medical Foundation. So you go to Palo Alto Medical Foundation

and find out what the deal is there, so that's more of a pointer. The other interoperability though is somehow you're exchanging information, in other words, you're sending information back and forth but it's really between the EHR, it's not really between the state of California and the state of Connecticut, for example, sending data back and forth.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Good point. It is probably pointers versus truly exchange and the interoperability needed in true exchanges that will be more the EHR to ILPD.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Neil?

Neil Calman – Institute for Family Health – President & Cofounder
Two quick points, one is, I guess this is for Gayle. The NPI numbers and license numbers are available on the Web. I just looked up my own just to make sure I was saying the right thing. You just go on the Web, find any medical license number for any state, find your NPI, and there's at least ten different services that provide NPI numbers. I looked it up on four different Websites, and for $1,350 you can find any DEA number, you just have to subscribe to the service and be a pharmacy. I just found that too. So these are not secure pieces of information now. I say that to highlight two things, because we always talk about security but we neglect to also look at other places where the same information that we're trying to lock down is available openly. So before we try to lock down something that people can get on the Web, we should probably look at that.

The second thing is really more of a question, and that is, how will the systems know what the capabilities are on the receiver end in relationship to technology? If I look on the system, how do I know what I can send? I can send a message but I don't know whether the person's got a computer system, an EHR, e-mail.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
This was one of the questions we had when we were developing the recommendations on the ELPD, the entity level. One of the recommendations was that the content of the record of an organization in the entity level provider directory will describe, will include, in a very structured way, what we call information exchange capabilities, meaning basically I am this organization and I am able to receive messages using these specific content structures, so it's a CDA version 2.0. You can describe in detail the kind of messages that you can receive, and the intent of doing that is to allow the submitter to discover what kind of message capability the receiver will have. So that's intended to be part of the record of the entity in the entity level provider directory.

Neil Calman – Institute for Family Health – President & Cofounder
So is a provider working intentionally in different entity locations, I can have some places where I can receive information electronically and other places where I might not?

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Absolutely.

Neil Calman – Institute for Family Health – President & Cofounder
And it would be updated?

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Yes.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Larry, and then Judy?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

Again, a huge amount of work's been done here, and thank you for that work. Most of my comments are actually around the context of this, because I think that the need for directories is absolutely critical and to manage them well is important. These comments are more around the edges, but I think they're important edges. One piece that's harkening back to an earlier discussion today about security, that we're really talking about identity management here, at least that's my take. This is a very key piece of that and so I'm wondering if we shouldn't be incorporating more information and more guidance here about the identity piece of this, how the information about Larry Wolf actually is about Larry Wolf and getting that part right.

A second piece is in addition to the state efforts and the fact that every organization is doing this for their own systems, we also have a federal initiative specifically to direct projects that's looking to hook up providers to providers, and I wonder if you could talk about that piece. One other point I want to get out there and then we can back up the comments, and that's a question about the fundamental use cases where we're going provider to provider. Because while I can imagine a lot of very clear examples of the exact person, the provider actually generating the content and generating the message, often the recipient is an agent for the provider, it's the provider's office. It doesn't go to Dr. Calman or to Dr. Tang, it goes to their office, and the office staff sort it out and figure out, oh, this is about this patient. Let me hook it up to the right record and let's see when that person's coming in. And they do a bunch of stuff and they need to see the content and they can't just see the wrapper. They actually have to look inside of it to be useful. So when the doctor shows up they're in context and the information's in context and the thing moves forward.

But if we actually start sending this strictly provider to provider, a narrow sense of that, we're actually going to be forcing people to break the security rules to do their job, and that's not our intention. We've got to recognize the complexity. So I think our use cases actually minimize the complexity. I don't know that they're actually critical to what you're trying to achieve here, but I'm kind of concerned that if we continue to propagate those use cases we're going to miss—

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Yes. Maybe I should clarify the intent really of the ILPD is to support the exchange when an individual that is seeking to communicate with another individual knows who they want to talk to but they don't know where they need to send the information. So the ILPD supports the exchange, and when we say individual to individual I should point out we're really not talking about doctors mis-sending it to Dr. Jones, but it's ultimately Dr. Smith looking at, I see various Dr. Jones so is this the right one. Then I see this Dr. Jones, which is the right one, has many locations, so this is the right location, so I now go to the ELPD, to the entity level provider directory record of that location, and pull out the information to send the information to that location. So it's not the ILPD, the individual level provider directory is not being used to connect literally directly to individuals, but it's really to allow the discoverability of where to send the right information, I think. I don't know if that helps clarify.

Neil Calman – Institute for Family Health – President & Cofounder
I guess it does. But I guess I feel like there's actually an identity piece that's a very core function to this as well.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Absolutely. There is a—

Neil Calman – Institute for Family Health – President & Cofounder
Got it.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
—... about the importance of adding more clarity.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Judy?

Judy Faulkner – Epic Systems – Founder
I think I'm following up on both Gayle and Larry. I think for the EHR HIEs, we really need this stuff out there. It would be cheaper. I'm going to assume that the standalone non-EHR HIEs will also find it less expensive because if you're trying to connect and you don't have this information, you've got to do interfaces which are time consuming and expensive. That's why the vendors have been able to write HIEs to themselves, because they have this information and haven't really been nearly as easily able to write HIEs to other vendors because this isn't standardized yet.

Then following up on Larry's, and maybe you answered this, maybe I'm just missing it, but my observation has been that if I go to healthcare organization X and I see Dr. X, and Dr. X is supposed to send something to Dr. Y at healthcare organization Y, the more important thing is the organization not the doctor. So if Dr. Y has gone somewhere else and now has moved, it shouldn't go to where he's moved. It should go to organization X, not to Z where he's moved, because that's where the information needs to go. That is the organization I go to. It doesn't follow the doctor; it follows the organization. That's why as I read the scenarios I get a little bit confused that are we really following the doctor and trying to find his right place when we should be following the organization.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
I would probably argue that it's probably both. In some cases, we need to follow the doctor because a doctor practices in different places and the record of this patient for this doctor is in this place. Basically, what we're saying is that we discovered the location through identifying the doctor and then recognizing which is the right place.

Judy Faulkner – Epic Systems – Founder
But if I go to, like in Wisconsin I go see Group Health in Madison and then they send me to UW, and if they send my records to UW and the person at UW has left, they should still send my records to UW, which does specialty work.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Absolutely, if the doctor—

Judy Faulkner – Epic Systems – Founder
Because this way they might end up sending it elsewhere.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
In that scenario, if the doctor has left and the patient doesn't have any more relationship with that doctor then that's right.

Judy Faulkner – Epic Systems – Founder
Right.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
But if the doctor has left and is moving that record with—

Judy Faulkner – Epic Systems – Founder
The records still should be going to, in my situation, should still be going to UW—

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
... doctor—

Judy Faulkner – Epic Systems – Founder
... orthopedist.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Exactly. I think that's a good point. We need to probably clarify that too in the scenarios, yes.

Judy Faulkner – Epic Systems – Founder
Okay. Thanks.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Good point. Any other comments, questions? Thanks again for—oh, Jodi?

Jodi Daniel – ONC – Director Office of Policy & Research
I just had a quick follow up on some of the conversation that was already here. One thing that would be really helpful is to understand, you talked about these being best practices to help provide guidance to the states, to tease out which are best practices and whether there are certain things that are not just best practices but must-haves as opposed to nice-to-haves. Also, if there are specific things that should be tied. For example, to governance as a baseline requirement or anything like that, to have a sense of how you're looking at these recommendations and which ones are, this is really a best practice or this is sort of a baseline must have and how it's connected with some of the other activities that we have beyond just the state HIE work.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Good point. Clearly, this is something, we were talking about earlier with a few people, clearly there is a need to define standards for some aspects of the provider directory, like the structure and the data elements and those aspects. There's then the operational processes by which an entity that is operating an ILPD should follow, and there's a distinction between some of the things that are must follow and then other ones where it would be nice if you follow.

Jodi Daniel – ONC – Director Office of Policy & Research
Right, if there are certain things that are necessary for interoperability, versus these are nice-to-haves, versus there may be some variability in certain of these areas. I think there's a little bit of all of that here.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
All of that ..., yes.

Jodi Daniel – ONC – Director Office of Policy & Research
Just teasing that out. I don't think it's a matter of re-doing the recommendations but just highlighting how you anticipate them applying.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Yes, absolutely. Thank you.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Gayle?

Gayle Harrell – Florida – House of Representatives
One more comment, please, and then also a question along that same line. I think part of these recommendations may fall into the governance aspect of an HIE, so I think perhaps identifying those elements and then making sure that that is transmitted to the Governance Workgroup would be absolutely essential. I would then ask, when will we have some recommendations coming forward from the Governance Workgroup?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
I think Dr. Blumenthal indicated they're in the NPRM process right now, actually, that they're going to be proposing their regulations. That is NPRM, so that means recommendations from here can still influence the final rule.

Gayle Harrell – Florida – House of Representatives
Right, so if there are recommendations, say, from this group that we should begin considering for purposes of the governance rule, it would be helpful to know what those are.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Thanks again for the comprehensive work. I think in preparation for next month's vote on it, it may be helpful to divide them out, and maybe consolidate some and talk about the policy, the standards recommendations that can go off to the HIT Standards Committee. The operations is a little bit more variable, but there are some key policy aspects that affect operations, but maybe not have 50 ....

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Will do.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Thank you very much. I appreciate it. At this point, I think we're ready for public comment.

Judy Sparrow – Office of the National Coordinator – Executive Director
If anybody in the room wishes to make a public comment, please step to the microphone here on the table. Please state your name and your organization. There's a three minute time limit. Carol?

Carol Bickford – ANA – Senior Policy Fellow
I wanted to address the Quality Measures report that identified the pressure ulcer measure as being a hospital associated condition under the Patient Safety category. When we submitted that proposal, we looked at it as being not hospital acquired but across full spectrum of care delivery and transitions and so on. I'm concerned that there might have been a misinterpretation of that intent. So that raises the question, are other measures as are recorded here and categorized, perhaps in the same vein, incorrectly represented. It's just a concern of those of us who are submitters.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you. Anybody else? Yes, sir.

Mike Peters – ACR – Assistant Director, Regulatory and Legislative Portfolio
ACR is a professional association representing over 34,000 radiologists, radiation oncologists and others. I just wanted to offer a few quick comments. There is a need in the patient provider communities for access to diagnostic images and associated data via EHR technology. By associated data, I mean structured radiologist reports, imaging history, and radiation dose information. Radiology practices nationwide are already well beyond the tipping point in terms of digital infrastructures, and most can provide Web-based images. The numerous benefits of including this data are obvious, fewer studies ordered, lower healthcare costs, and lower cumulative radiation exposure for patients.

I also wanted to express that obviously meaningful use is not truly meaningful for radiologists and other specialist EPs. There are over 30,000 in our community who are eligible, and this must be addressed in stage two through specialty specific MU pathways. While we understand why the Policy Committee focused on certain subsets of EPs in stage one, the lack of radiology related discussions in advance of stage two is extremely concerning. I also just wanted to say real quickly that the stage two rule making is really the last opportunity to get this right before it becomes an unfunded mandate on specialists who were neglected by the first two stages, so this isn't just a transition to stage three, this is really important. Thank you.

Judy Sparrow – Office of the National Coordinator – Executive Director
On the phone, we have Bill Brethwaite.

Bill Brethwaite
Hi, this is Bill Brethwaite. I have three comments about the strength of passwords, about multi-factor authentication, and about the question that came up about biometrics. First of all, the question about strength of passwords, I think the strength of passwords is not in their size or their complexity, it's about the fact that they can be guessed. So they have to be non-dictionary, non-name kinds of passwords, and they're shared, they're recorded by key loggers, they're extracted by phishing, by malware, there are lots of risks to passwords that have nothing to do with their strength. In fact, I haven't seen any evidence at all that making a password greater than four or five characters that's a non-dictionary, non-name

password, actually increases its strength or its value. So I think passwords by themselves are powerful, but what we've been doing is making people write them down and making them more risky than what we started with.

The second comment about multi-factor authentication is that there are many ways of doing this that are risk-based and that are flexible. That is, there's static risk-based decisions about if you're in the clinic and there are other factors involved, to make sure that you know who it is, who's logging in, and maybe you don't need more than one factor to do that. That's a risk-based decision. But the rationale for doing that ought to be transparent and there ought to be considerations about the time to log in and the hassle to use it and so on built into that risk-based decision.

There are also dynamic factors. You can use device registration mechanisms. You can require second factor authentication once a day or once a week, and only challenge when something changes. If a doctor logs in at the beginning of the day and at noon, he picks up a computer and walks over to Starbucks and logs in from a different ISP, you've got to do a two factor authentication again. That dynamic, risk-based authentication mechanism is available and very useful. Also, based on the risk of the application and what the intent of the access is, if you're going to do electronic prescribing for controlled substances, then you've got to meet the DEA rules for a very high level, maybe missed level of assurance, 3.5. But if you're just going in to read something as opposed to changing something or looking at one record instead of many, that risk analysis may require a different level of authentication.

The third comment about biometrics, I think the comment here was is biometrics alone sufficient. I think that depends on a couple of factors, including the fact that biometrics requires a reader or an interpreter of some kind. The threat isn't so much the biometric itself, because the software that interprets the biometric can be triggered at a particular level. It's about whether or not the device can be compromised by malware or spoofed in some mechanism which is when you would want to go back and do a two factor mechanism. Overall, I think the same considerations would apply to patient versus provider applications. You end up with different requirements if you do the risk analysis, but the same consideration should be applied.

I think we do need more details than HIPAA supplied. Remember, the HIPAA security rule was written back in 1998, that's well over a decade ago, and we do require our people to have more details about how they should do this because as we start to exchange information, as was discussed, trust is the major issue, and the weakest link is the maximum of trust in our systems. So we have to make sure that this authentication mechanism, which is going to be a commodity here, this is not going to be some fancy new authentication method as it has been in the past, this will be a commodity in every EHR system and every PHR system in the near future and we've got to get it right. Thank you.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you, Bill. We do have a comment in the room.

Corinne Rubin – American Academy of Otolaryngology, Head and Neck Surgery
Hi. Thank you for providing me with the opportunity for public comment. My name is Corinne Rubin with the American Academy of Otolaryngology, Head and Neck Surgery. My comment is in regards to the ILPD and the recommendation of filtering physician data with PECOS. I would urge caution with moving forward with PECOS data until CMS' infrastructure is able to handle such information. As we've seen with the first iteration of the physician compare that went live in January, a lot of the information that's posted on physicians is incorrect or out of date. CMS has stated that it's from data that was populated in the spring, however, we've heard from physicians that have been in PECOS for over a year and still has out of date data, often years old. You need to think of a way to make sure that CMS has the necessary infrastructure so data is filtered correctly and a way for physicians to be able to easily update their data and it comes into the system in a timely fashion. Thank you.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you very much. Any other comments? Yes, sir?

Arun Chadri
Hi, this is Arun Chadri from .... I just have a couple of quick comments on the security side. Like the previous gentleman said, two factor authentication is good, but it can be used intermittently. A good example might be that the first time the doctor logs in, in the morning would be a nice time to double-check, but the rest of the day you wouldn't do it. The other thing is that in a past life I looked at biometric solutions very, very carefully and they are good but I'll also leave one question out there. What happens if your biometric database gets compromised?

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you. One more comment.

Jonah Houts – Express Scripts
Great. Thank you very much. My name is Jonah Houts and I'm with Express Scripts. We're a pharmacy benefit manager. I actually have a specific concern about electronic prescribing as it relates to health IT. Express Scripts knows firsthand how electronic prescribing has increased patient safety, improved efficiency in practices and hospitals across the country, and a lot of this was done because of organizations like this committee and efforts by Congress through ... to encourage doctors to, or rather prescribers at large to adopt these technologies. Unfortunately, 18 different states right now are considering legislation that would create a 50 state patchwork of inconsistent ePrescribing standards. These requirements actually cannot be supported by the current standards that have been developed by NCPDP, thus we're leaning towards a rapid unraveling of the country's ePrescribing system. We think this is a slippery slope for providers, who actually will face a one percent cut in Medicare reimbursement next year if states adopt these standards, but also a slippery slope for legislators and organizations like this to be aware of how these standards can be modified on a state by state basis.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you very much. Dr. Tang, back to you.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Very good. One of the rewarding things about being on a committee like this, ... committee it's the robust discussions we have among ourselves, and the other piece is what we learn from public comments and through all the written comments in response to all of our proposals. So it's a very active and healthy activity, I think that we've been involved in. I want to thank this group, the committee members, the workgroup members, the public, and especially the ONC staff that just make it happen, not only make the meetings happen but then have to go make what we suggest happen. So thank you everyone and see on – I've got to warn you all, April 13th is going to be a long day. We're going to have a follow up from the Meaningful Use Committee digesting all of the meaningful use comments, we'll have a final from the PCAST Workgroup, is that correct?

Paul Egerman – Software Entrepreneur
Hopefully final.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Hopefully final. We'll have the Information Exchange Workgroup come back with their final proposals for approval, and I understand we'll have the Privacy and Security personal authentication discussion. So count on a long day. In fact, I don't know quite how we're going to fit it all together, but just count on being here for a while. Thank you very much and safe travels.

Public Comment Received During the Meeting

1. Why can't we define methods of COMMUNICATING the Level of Assurance used in a way that on a transaction-by-transaction basis the access control decision can be made? Thus make it required to include trustable LoA value, but not mandate a specific LoA?!?!?!?!?!

2. Is the scope of this committee, all possible use-cases for remote access (e.g. to their own organizations provided EMR)? Or is it focused on remote accesses to the greater HIE?

3. Note that when it comes to User Authentication, one must not just consider the Security Risks but also the Risks to Patient/Operator SAFETY. Specifically false-positive access - denying access due to authentication issues - for many workflows simply means delaying some transaction (bank transaction, patent filing, etc); whereas this same delay in treating a patient can cause Pain, Harm, or even death for specific workflows.

4. Authentication and Level of Assurance: Don't mandate a specific LoA, mandate LoA be a part of Identity http://bit.ly/ebMxvO